Welcome to Docu-MART User Assistance

Docu-MART (Document - Management Authoring Review and Tracking System) provides a variety of user-assistance and help functions. This Online Help features screen-level assistance, screen element information, and supporting help for each procedure.

Information in Docu-MART Help can be accessed using the Contents, Index, or Search buttons at the top, left side of this screen.

- By default, the table of **Contents** is displayed in the panel to the left of this screen. Click a book icon to expand it and display the topics it contains. Click the topic you want displayed in this space.
- Using the **Index** allows you to type a keyword to narrow the list of topics displayed to those containing that keyword.
- Using the **Search** functionality, you can type a keyword to display a list of topics that contain that keyword of keywords. For example, after entering **Reviewers** and clicking **Go**, all topics containing the term Reviewers display.

If you encounter problems working with Docu-MART, please contact the CTEP Help Desk for a quick resolution.

To contact the CTEP Help Desk:

- Email at ncictephelp@ctep.nci.nih.gov.

Docu-MART User Roles and Functions

Function	**Site Coordinator**	**Protocol Specialist**	**Reviewer Site Lead**	**Reviewer Site Reviewer**	**Reviewer CTEP Lead**	**Reviewer CTEP Reviewer**	**Author**
Authoring Tool							
Authoring Tool	Full Access	N/A	N/A	N/A	N/A	N/A	Full Access
Publish Module							
Upload Document	R/I/U/D	N/A	N/A	N/A	N/A	N/A	R/I/U/D
Assign Reviewers	R/I/U/D	R/I/U/D	R/I/U/D *	R	R/I/U/D *	R	N/A
Create Timelines	R/I/U/D	R/I/U/D	R/I/U/D ^	R	R/I/U/D ^	R	N/A
Tasks Module							
Tasks	R	R	R	R	R	R	N/A
Inbox Module							
Inbox screen	R/U/D	R/U/D	R/U/D	R/U/D	R/U/D	R/U/D	N/A
Review & Commenting Module							
View/Edit Reviewers	R/I/U/D	R/I/U/D	R/I/U/D *	R	R/I/U/D *	R	N/A
View/Edit	R/I/U/D	R/I/U/D	R/I/U/D	R	R/I/U/D	R	N/A

Timelines			^		^		
Review & Commenting	R/U/D	R/U/D	R/U/D	R/U/D	R/U/D	R/U/D	N/A
View Document	R	R	R	R	R	R	N/A
Add Comments/Replies	R/I	R/I	R/I	R/I	R/I	R/I	N/A
View My Comments	R/I/U	R/I/U	R/I/U	R/I/U	R/I/U	R/I/U	N/A
View All Reviewer's Comments	R/I	R/I	R/I/U	R/I	R/I/U	R/I	N/A
Executive Summary	N/A	N/A	N/A	N/A	R/I/U/D	N/A	N/A
Full Comments Report	R	R	R	R	R	R	N/A
PRC Report	N/A	R	N/A	N/A	R	R	N/A
Site Consensus Report	R	R	R	R	R	R	N/A
CTEP Consensus Report	R	R	R	R	R	R	N/A
Site and CTEP Consensus Report	R	R	R	R	R	R	N/A
Previous Versions Report	R	R	R	R	R	R	N/A
Reviewers Task Status	R	R	R	R	R	R	N/A
Set My Preferences	R/I/U	R/I/U	R/I/U	R/I/U	R/I/U	R/I/U	N/A
Resolve and Change Status of Comments							
Added to the CTEP CR	R	R	R	R	R/I/U	R	R
Draft	R/I/U/D $	R/I/U/D $	R/I/U/D $	R/I/U/D $	R/I/U/D $	R/I/U/D $	N/A
Submitted	R/U $ &	R/U $ &	R/U	R/U $ + #	R/U	R/U $ + #	N/A
Withdrawn	R/U $ &	R/U $ &	R/U $	R/U $ + #	R/U $	R/U $ + #	N/A
Rejected	R	R	R/U	R	R/U	R	N/A
Accepted	R	R	R/U	R	R/U	R	N/A
Incorporated	R/U	R	R	R	R	R	N/A
Not Incorporated	R/U	R	R	R	R	R	N/A

R = Read Only; I = Insert; U = Update; D = Delete
* = Only if Change Reviewer flag is set, otherwise Read Only.
^ = Only if Change Timeline flag is set, otherwise Read

Only.
$ = Only if he is the Owner of the comment, otherwise Read
Only.
= Non Facilitated
& = On behalf of facilitated Reviewer

CTEP Submission - View/Edit Reviewers

1. The Protocol Specialist performs notification to reviewers about the published document.
2. After the document is published, the PIO receives an email notification that is copied to the Site Coordinator. No reviewers on the document receive any email notification until the Protocol Specialist performs the 'published' notification.
3. Once the document is published, the PIO Protocol Specialist can view the document on the Tasks screen, with the associated Assign Reviewers/Timeline task.
4. The Protocol Specialist must link to the NCI document (from PATS) to add reviewers.
5. When the Protocol Specialist links the document to this NCI document, the latest CTEP review information populates automatically and that Protocol Specialist is assigned as the Protocol Specialist for the document.
6. Once Protocol Specialist is assigned as the Protocol Specialist on that document, no one else can see the see that document until notify that the document is published. Also, if a Protocol specialist adds another Protocol Specialist, the new Protocol Specialist can then see the document.

Delegated By Roles

On the Tasks screen, two different column titles can display for the roles column.

The Site Coordinator and Protocol Specialist see **Delegated By Role(s)** as the column title, while other users see **Role(s)** as the column title,

1. **Delegated By Role(s)** -- Site Coordinator, Protocol Specialist

   If the actual name of a person is featured under the Delegate by Role(s) column, that person is delegated and their role(s) on this submission appear directly below the name.

2. **Role(s)** -- All other Docu-MART users

   Only the role for this submission displays in this column.

Tasks

Click link to advance to section or scroll down:

Introductio n	Purpos e	Key Processes and Concepts	Steps	Additiona l Features	Screen elements

Introduction

This is the first screen to display when Docu-MART is accessed. This screen lists the tasks for each document and provides links to the appropriate screens. It is available to every Docu-MART user. Screen content and available links are dependent on the user's role[1] and authorization[2] level. Task screen elements are used for filtering and identifying specific tasks information.

Purpose

The Tasks screen is used to review and manage published documents. The documents are separated visually by alternating blocks of color.

Tasks are displayed in this order:

1. Documents that have any open tasks, ordered by latest due dates.
2. Documents that have all tasks closed ordered, by latest task closed dates.

Key Processes and Concepts

- The Tasks screen can be accessed at any time by clicking the Tasks tab.
- By default, the document review tasks on which the Protocol Specialist is assigned displays. If someone else is the assigned Protocol Specialist, the 'Assign Reviewers/Timelines' tasks displays. This allows the Protocol Specialist to add himself/herself and others to the review at any time during the review.
- Documents with open tasks display first, ordered by latest due date. Documents with all Tasks closed display next, ordered by the latest task's due date.
- A document[3] can have different versions. Different versions[4] have

[1] Assignment for this document.
[2] Which activities can be performed on this document.
[3] A document can be a Concept, LOI, or Protocol.
[4] Different document instances at different times, usually based on changes.

different submission types. Different submission types[5] have different tasks.

> ***Note:*** For each submission you will have separate tasks (Review & Comment, Incorporate Comments, and so on). The tasks are per submission for a version of a document

- If the reviewer is delegated, the reviewer tasks will be added automatically to the Site Coordinator or Protocol Specialist.
- The Delegated By Role(s) column appears for Site Coordinators and Protocol Specialist, while the other users see the comparable column title of Role(s).
- For the Protocol Specialist:
    - If there are no CTEP reviewers assigned, there will be a link available to the Protocol Specialist from the task screen to add the reviewers.
    - Protocol Specialists have an additional option in the filter that allows filtering by Protocol Specialist, since they have access to all documents published for CTEP Review.
- The user can filter their tasks based any of the following:

    Document Type

    NCI Document Number

    Local Document Number

    Phase

    Organization

    Submission Type

Steps

1. In the Tasks Due Date column, click the link to the appropriate task (such as: Review, Comment & Reply by Site, Resolve Comments, Incorporate Comments, and so on). The screen for the selected task displays.

Additional Features

Sorting:

1. Click a column heading to re-sort the entries based on that column.

[5] What kind of review is required and by whom.

Filtering:

1. Click **Show Filter** to display the filtering fields.
2. Enter text or use the drop-down lists to filter. Text is not case-sensitive. A wild card can be used. Location of the wild card relative to search criteria yields different results. The wild card may be placed before or after characters, or sandwiched between.

   For example, entering %23 in the Local Document field will display every document whose number ends in 23, but entering 23% in the Local Document Number field returns every local document number that starts with 23, ending in anything.

   A combination of filtering fields can be used.

3. Click the appropriate filtering button:

- **Open**: Lists all reviews with an open status meeting the search criteria.
- **Closed**: Lists all reviews with a closed status meeting the search criteria.
- **All**: Lists all reviews meeting the search criteria.

Note: Protocol Specialists have an additional filtering field.

4. Scroll through this narrowed list if necessary.
5. Click **Hide Filter** to remove the filtering fields from view (optional).

Viewing All Tasks

When the Task screen displays, by default it shows all open reviews. To see all tasks, even if the review is closed:

1. Click **Show Filter**.
2. Click **All Reviews**.

Title Link:

1. Click the Title link (featured with 'Click for more') to display information for the document version, such as the full title, as well as Agents, Diseases, File Information, and Additional Attachments (if they currently exist). A document information window displays.
2. Click the **View** button to the right of the component to display view-only information. For example, after clicking on the View button for 'PSW file', the PSW is displayed. Click the 'X' in the upper right corner to close this window.

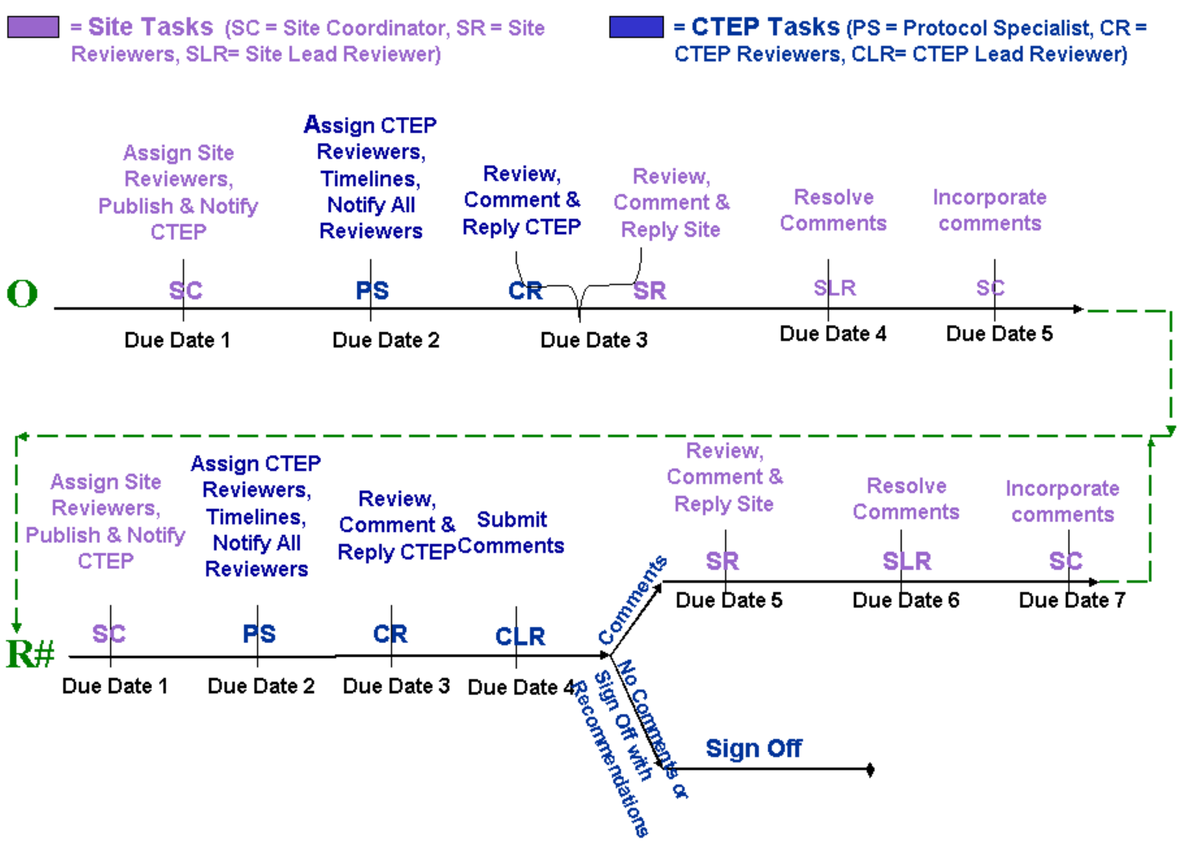
Tasks screen elements

The following elements are featured on the Tasks screen. Some appear twice, as selection items and column headings.

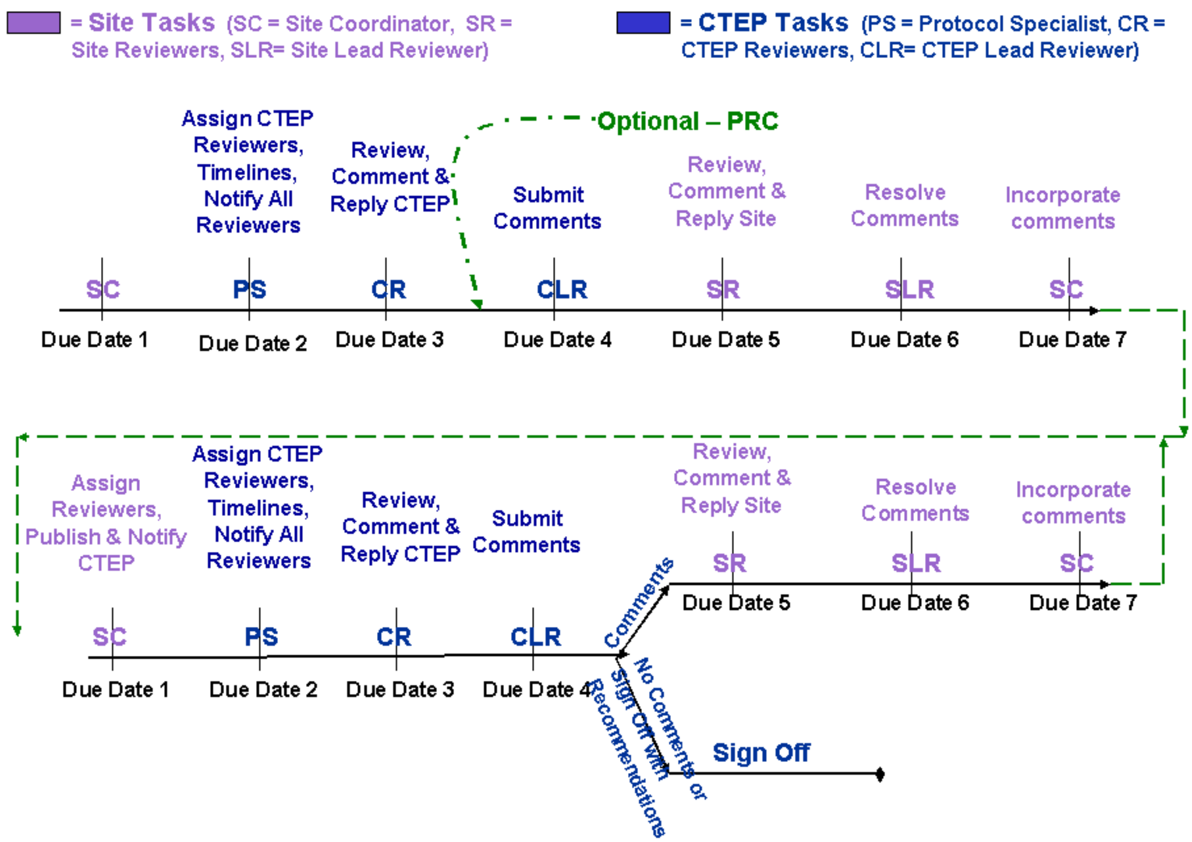
Field	**Entry Method**	**Description**
Document Type	Drop-down list (using Filter)	Category, or type, that describes this document.
NCI Document #	Direct Entry	Unique identifier for a document. If the document is submitted by a group, the group document number is used. If not, the identifier is system-generated.
Local Document #	Direct Entry	Identifying code for this document, as determined by its initiating group
Phase	Drop-down list (using filter)	Phase of the document to be located.
Docu-MART Authored	n/a	(Docu-MART logo) indicates that the document is Docu-MART authored.
Version Date	n/a	Date this version was created.
Organization	Drop-down list (using Filter)	Group responsible for the creating of this version of the document.
Submission Type	Drop-down list (using Filter)	Category or qualifier for this submission (Regular, Expedited, and so on).
Review Status	Drop-down list (using Filter)	Current status of review, 'Open' or 'Closed'.
Show Documents	Drop-down list (using Filter)	For Protocol Specialist only, filter criteria allows viewing selections of those assigned only to the PS,

		assigned to others, or all.
Roles(s)	n/a	Assigned personnel function(s), or role, for this submission.
[Delegated By Roles(s)]()	n/a	Delegated personnel function(s), or role, for this submission, available only to Site Coordinators and Protocol Specialists.
Tasks Due Date	Click link	Tasks to be performed for this submission, with its due date.
My Status	n/a	Current status of tasks assigned to you.

CTEP Submission - Collaborative



CTEP Submission - Sequential



Email Actions

Comprehensive notification of all Docu-MART activities is required to continue the document's forward progress. Based on submission tracks and roles, notification is provided by automatically sent Emails.

Stage Tasks - Email Recipients provides a quick guide that cross-references the Stage Tasks with the User Roles. It does not provide additional or supporting information. See Using a spreadsheet for information on opening the spreadsheet, along with important 'readability' suggestions.

Using a spreadsheet:

1. Click on the link. The Excel spreadsheet displays in .pdf form.

Readability suggestions:

a. Maximize screen if necessary.

b. Change size of spreadsheet by clicking on the drop-down list of the Size % field (near the top of the screen) and select a larger size such as 100% or 125%.
c. Use the bottom scroll bar to scroll right or left.
d. Move the left margin of the spreadsheet to the left, toward the Bookmark tab. The contents of this tab are important, but the Bookmark items in the Bookmark can be seen in their entirety by 'hovering over' the item with the mouse pointer.

To display the appropriate entry:

1. Click directly on the topic name in the Bookmark tab list, such as Add/Edit Reviewers, Review, Comments & Reply topics, Submit Comments topics (and so on). The selected entry will then appear on the screen.
2. Repeat if necessary.
3. Close the spreadsheet to return to the Email Actions online help topic.

Inbox

Click link to advance to section or scroll down:

Introducti on	Purpos e	Key Processes and Concepts	Steps	Additional Features	Screen Elements

Introduction

The Inbox provides the ability to receive and read emails that inform Docu-MART users when a relevant activity has occurred. If authorized, the user can edit and approve emails. This function is date-driven, and a specific role's authorization indicates what actions can be performed here.

Purpose

This function provides notification (emails) about documents to be reviewed, changes in timelines, and so on. The emails are listed in chronologic order, most recent first.

Key Processes and Concepts

- The emails received depend on the assigned role. This concept is key to understanding Inbox functions. Review the Email Actions to learn how the complete email cycle is executed.

- A yellow envelope near the left side of the screen indicates that the email has not been read. A paper clip indicates that there is at least one attachment
- The From column displays the role of the sender, not the sender's given name.
- An **Edit** button is featured to the right of all actionable email items.
- All automatic emails are sent by batch at the appropriate time. Previously-entered dates, such as those in the Create Timeline function, direct most of the scope and timing of each email.
- 'On the spot' edited emails, allowed by some roles, are sent by the user or deferred for later sending. In this case, clicking **Save** will not only save the edits, it will indicate that the email is to be sent by batch at the appropriate time.
- Site Coordinators and Protocol Specialists can approve emails.

Steps

1. To view an email, click on the Subject link.
2. Some emails are associated with an Edit button. The privilege to edit is role-specific. To edit an email, click the **Edit** button to the right of the email header (if available).

   2.1 Editing an email

   a. Click **To:** to add recipients to the email
   b. Click **Cc:** to add recipient copies.
   c. If necessary, use direct entry to add an Additional Cc or Bcc.
   d. Click **Browse** to select the file to be attached. The browse feature works like traditional browse functions.
   e. Click **Attach**.
   f. Enter a message in the Additional Text Area.
   g. In the actual email, click the Refresh Data button to bring in new data, such as a timeline change. Use cautiously because it can also eliminate any newly entered text (optional).

Additional Screen Features

Sorting:

1. Click on the ‘Subject’ ‘Received’, or 'From' headings to re-sort by the selected column heading

Navigating:

1. Click the First, Previous, Next, and Last red arrows (or the page numbers) to navigate to the other email listings for the document.

Archiving an email:

1. Click on the appropriate checkbox in the Archive ? column to select the items to archive. Multiple emails can be selected at the same time.
2. Click **Archive Checked Items** (upper right hand side of the screen) to archive.
3. To view archived emails, click **Show Archive** (optional).

Clear All/Select All:

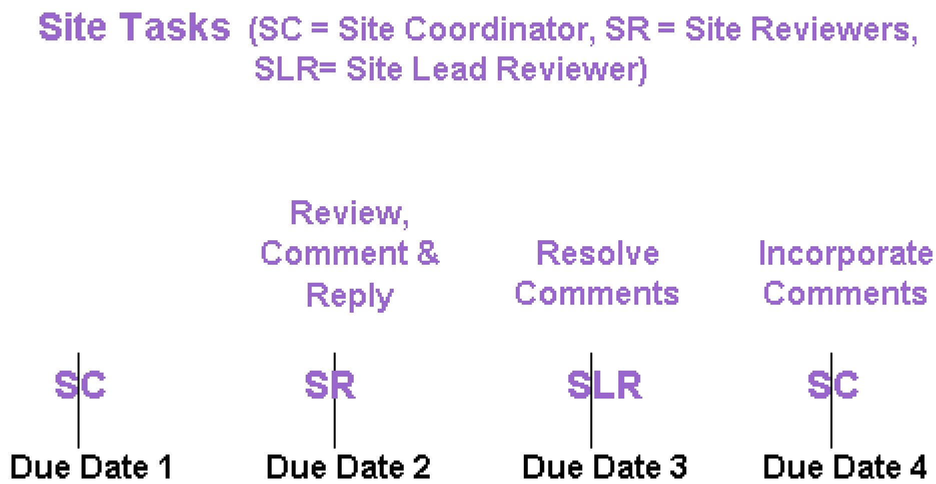
Multiple emails can be selected at the same time. Clicking **Select All** enters a checkmark in every Archive ? checkbox, while clicking **Clear All** removes those checkmarks.

Inbox screen elements

The following elements are featured on the Inbox screen:

Field	How to Use	Description
Archive ?	Click checkbox	Email is to be removed from the Inbox and placed in the archive.
	n/a	Indicates associated email has not been opened.
	n/a	Indicates associated email has not been opened.
Subject	Click link	Purpose or title of the email, provides access to email contents.
From	n/a	Role of person sending the email.
Received	n/a	Date the Inbox received this email.

Pre-submission



Submission Tracks

Three submission tracks are available in Docu-MART: Pre-submission, CTEP Submission - Sequential, and CTEP Submission - Collaborative.

Links are provided here to screens containing a graphic representation of the processes and players involved in developing and submitting a Docu-MART document.

Understanding the Submission Tracks Graphs

- The type of Submission Track is featured at the top.
- Submission tracks are **due date** driven. This is based not on a specific date (as shown in the Create Timeline function), but in intervals--such as Due Date 1, Due Date 2, and so on.
- Site Tasks are featured in violet, CTEP Tasks in royal blue.
- A legend for the abbreviations appears after the title, such as 'SR' for Site Reviewers and 'PS' for Protocol Specialist.

Submission Tracks Graphs

Pre-submission	CTEP Submission - Sequential	CTEP Submission - Collaborative

Assign Reviewers

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

Reviewers must be assigned to every document. A reviewer can be previously listed reviewer, or one can be added using this screen. Each reviewers must be authorized to perform specific functions as determined by the associated level of authorization.

Purpose

The Assign Reviewers screen, designed for the Site Coordinator, manages the assignment of reviewers to the document. This screen is also used to designate their role and authorization to change statuses.

Key Processes and Concepts

- By clicking the **Add** button, a window containing a selection list of the site-specific available reviewers displays. After selecting a reviewer, a role must be assigned to that reviewer.

  You can add a reviewer that is not already specified as an available reviewer. However, you want to be certain that the reviewer's name is not already included.

- By clicking the **Add Unlisted Reviewers** button on the Reviewers window, you can add other reviewers to this document. The Delegated checkbox is selected automatically for that reviewer.

Note: Assigned roles play a key part in the Publishing function.

Previous[6] ***and*** **Next**[7]

Steps

1. Select the Submission Type.

[6] Before assigning reviewers you must have first uploaded the appropriate document using the Upload Document functions.

[7] You need to review the information, then create a timeline for completing the document.To get to that next screen, click the Next button or click the 'Create Timeline' disc in the left section of the Publish tab.

Note: For a Pre-submission, the submission number automatically populates with the sequential number.

1. Click the **Add** (Reviewing Team) button to display the Reviewers window.
2. Select the 'Organization' from the drop-down list or accept the default.
3. Scroll to the appropriate names or use the 'Search by' function if the list is long. To use the 'Search by' function, select the first name or last name of the reviewer to be used in the search. Enter that name in the text box to the right. Click **Go**.
4. Click the checkbox to the left of the appropriate name(s).You can select multiple names on this screen.
5. Click **Add Selected** to copy the reviewer's name to the Selected Reviewers section.
6. Click **Done** to return to the Assign Reviewers screen.

Each reviewer needs to be assigned a role or roles for this document. For example, a reviewer might be a Lead Reviewer on another document but a general reviewer and Site Coordinator on this one.

7. Click the appropriate **Role** checkboxes for each reviewer.
8. Click the appropriate checkboxes under the 'Authorize to Change' columns:
    - 'Timeline' allows this reviewer to create and manage timelines.
    - 'Reviewers' gives this reviewer the ability to add other reviewers.
    - 'Delegated' indicates that this reviewer grants the Site Coordinator the right to enter, add, and change the review text.
9. Assign priorities to the individual reviewers on a CTEP review by entering a number in the Reviewer Priority field next to each reviewer. The Lead Reviewer automatically receives first priority, and the Protocol Specialist automatically receives last priority.
10. When finished, click the **Save** or **Completed & Next** or **Next** button.

Additional Features

After a step is marked as complete by clicking the **Completed and Next** button, a Reset to Not Completed checkbox displays under the step name, featured in the Publish for Review box on the left. Clicking the checkbox, then clicking **Save** resets that step to 'not complete' and re-displays the **Completed & Next** button. This function is available until the document is published.

Adding an Unlisted Reviewer

If the reviewer's name does not appear on the list of reviewers, the name can be added:

1. Click the **Add Unlisted Reviewer** button on the Reviewers window.
2. Complete the fields on the Unlisted Reviewers window.
3. Click **OK** to return to the Reviewers window. The new reviewer is added to the Selected Reviewers.

Optional: To remove a reviewer, click the checkbox associated with that reviewer, then click **Remove Selected**.

Editing an Unlisted Reviewer record:

An unlisted reviewer record can be edited at any time.

Filtering (Search/Filter Criteria):

1. On the Reviewers window, choose the filtering criteria to be used in the search. These filtering options can be used singularly or in combination.

- **First Name**: Enter the complete first name or a portion of the first name. For example, if you know that the first name is Steven or Stephen but are not certain of the exact spelling, enter 'Ste'.
- **Last Name**: Enter the complete last name or a portion of the last name. For example, if you know that the last name is Smith or Smythe but are not certain of the exact spelling, enter 'Sm'. This field can also be left blank but it is not recommended.
- Select the appropriate **Organization** from the drop-down list. Select 'All' if the organization is unknown or to include every organization in the search.

2. Click **Go** to display the names meeting all of the search criteria.

Assign Reviewers screen elements

Document identifiers appear automatically near the top of the screen.

The following elements are featured on the Assign Reviewers screen:

Field	How to Use	Description
Submission Type	Drop-down list	Category or type of this submission, such as Pre-

		Submission[8] or CTEP Submission[9].
Submission Number	Direct entry	Group-assigned number for the submission. This field only appears if Submission Type is Pre-submission.
Select All Clear All	Click checkbox	Select all records in preparation for delete. Clear (uncheck) all records.
Reviewing Team	Click **Add** button	Clicking this button displays a 'select' Reviewers window.
Edit (Site Reviewers)	Click the Edit link.	Clicking this link displays the Unlisted Reviewers edit window.
Reviewer section:		
Delete?	Click to select	Indicates that this selection is to be remove from the assigned reviewers when the **Save** or **Completed & Next** buttons are clicked.
Reviewer	none	Full name of reviewer selected from the list of available reviewers (site- specific)
Role	Click checkbox(es)	Function of the reviewers for this protocol; Lead Reviewer, Reviewer, or Site Coordinator. The Site Coordinator selection is used by the actual Site Coordinator to

[8] When the document is finished it will be ready for internal reviewbefore it is submitted to CTEP.

[9] When the document is finished it will be CTEP-ready, and may or may not be submitted for internal review.

		delegate a 'substitute'.
Authorize to Change section		
Timelines	Click to select	This reviewer can edit document timelines.
Reviewers	Click to select	This reviewer can assign other reviewers to this document. These added reviewers must already exist in the Docu-MART database.
Reviewer Priority	Enter a number	Assign priorities to the individual reviewers on a CTEP review by entering a number in the Reviewer Priority field next to each reviewer. The Lead Reviewer automatically receives first priority, and the Protocol Specialist automatically receives last priority.
Facilitated (Cannot submit comments directly to external Reviewers)	Click to select	The document must be assessed by the Lead Reviewer before it is distributed. This reviewer cannot submit directly to other Reviewer groups.
Delegated (Task done by Site Coordinator).	Click to select	This reviewer grants the Site Coordinator the right to enter, add, and change the review text. This information will then be tracked by Reviewer and Site Coordinator.

Check Completeness

Click link to advance to section or scroll down:

Introduction	Purpose	Steps

Introduction

Docu-MART provides a mechanism to determine if required information is missing or incomplete. If there is missing or incomplete information for a Docu-MART authored document, a Check Completeness window containing relevant details displays immediately after completing the Confirm & Submit step.

Using the Check Completeness function and performing the steps featured here are mandatory for a CTEP Submission. However, it is optional for a Pre-submission, since a Pre-submission functions almost as a 'work-in-progress'. Pre-submissions can be submitted when incomplete, while a CTEP Submission cannot.

Purpose

The Check Completeness function on the Confirm & Save screen is used to confirm that all data elements were uploaded properly, with all required information complete. An error message displays that indicates which functions requires correction, Title Page Elements or PSW Elements.

Steps

1. Expand the File Information and download the DXW Document File. Open the file in the Docu-MART Authoring Tool application.
2. Select the appropriate option:
   - If there are pending Title Page elements, select **Title Page** from the Edit main menu item.
   - If there are pending PSW elements, select **PSW** from the Edit main menu item.
3. Complete the pending items.
4. Click **Check Completeness** to make sure there are no additional pending items.
5. From the File menu, click **Save for Publish**.
6. Return to the Docu-MART Publish screen.
7. Select the Upload Document step by clicking on the disc for the existing Publish record for that document version.
8. Click **Browse** to find the updated .dxw file and upload.
9. Repeat the Publishing steps and click **Completed & Next** after each step is completed.
10. Click **Save for Publishing** to republish the document.

Confirm and Save

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Screen elements

Introduction

This function allows all of the previously entered 'Publish' information to be examined at one time before submitting the document for review. Prior screens can be easily accessed if reviewing the document sections indicates that a change should be made.

Purpose

The Confirm and Save screen provides a view-only function to examine the all of the previously entered or attached 'Publish' information before submitting the document for review.

Key Processes and Concepts

The File Information section displays any attachments and also provides the ability to download the current document for printing, reviewing, and so on.

If there are attached PSW or Change Memo files, their names display when the File Information heading is expanded. If these two fields (PSW File and Change Memo File) do not display, no attachments were made during the upload process.

Each type of Document Information on this screen has a separate heading.

- To view the text for all headings, click on ▶, the right arrow key for 'Expand All'.
- To view the text for one heading at a time, click on ▶, the right arrow key associated with the heading.

If changes were made to any of this information, return to the appropriate screen to make the changes.

After completing the process of reviewing, and (if necessary), editing, click **Save for Publishing**. A message displays if a previous step has not been completed.

Previous[10] *and* **Next**[11]

[10] To be able to assess the contents of this view-only screen properly, you must have completed the three previous processes: Upload Document, Assign Reviewers,

Steps

File Information

1. Click the **View** button to the right of the selection (Document File or PSW File) to display view-only information.

   For example, after clicking on the **View** button for 'PSW file', the contents of the PSW display.

2. Click the 'X' in the upper right corner to close this window.

To download the current document:

1. Click the **Download** button to the right of the DXW Document File entry.
2. When the File Upload window displays, select the appropriate action (Open, Save, and so on).

Document information

1. To view the text for all headings, click on the right arrow key for 'Expand All'. To view the text for one heading at a time, click on the right arrow key specific for the heading.
2. If you need to change any of this information, return to the appropriate screen to make the changes.
3. After reviewing, and (if necessary), editing, click **Save for Publishing**. Edit Email, used to notify the assigned reviewers, then displays.

Confirm and Save screen elements

Document identifiers appear automatically near the top of the screen.

The following elements are featured on the Confirm and Save screen:

Section Heading	Contents Synopsis
After clicking the arrow to "Expand All"	

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and Create Timeline. However, any existing yet incomplete information will also display.

[11] Click the Submit button after reviewing this screen for accuracy and, if necessary, making any changes. Your document is distributed via email to the selected reviewers and you are transferred to you Inbox.

File Information	The file name entered on the Upload Document screen.
Document File	The text of the uploaded document.
PSW File	The text of the PSW file, if one was attached during the upload process.
Change Memo File	The text of the Change Memo file, if one was attached during the upload process.
Document Information	A summary of the document **identifiers** entered or selected on the Upload Document -> Specify Document Profile screen.
Agents	The Upload Document -> Specify Document Profile screen using the Agent **Add** button with its **Search and Select** function.
Diseases	The Diseases (MedDRA Code and Name) added on the Upload Document -> Specify Document Profile screen using the Diseases **Add** button with its **Search and Select** function.
Sections	The numbered headings and subheadings for the document. The final result is from a combination of the relevant document version template and any changes or additions made on the Upload Document -> Specify Document Sections screen.
Site Reviewers	The submission type, any other participants, and all reviewers assign by the Site Coordinator on the Assign Reviewers screen. role and authorization. Specific authorization levels are included.
Timeline	The duration and due dates for the four review and publish milestones,with their user-entered free form comments and number of days for reminder before the due date. This information was selected on the Create Timeline screen.

Create Timeline

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

User-designed timelines allow the publishing process to advance in a timely manner, while making all related personnel aware of due dates and timelines. This screen has automatic features that assist in timeline management and user notification. A Pre-submission timeline is created by the Site Coordinator. A CTEP submission timeline is created by the Protocol Specialist.

Purpose

The Create Timeline screen is used to create the suggested or recommended time frame for completing each step of the Publishing and Review process for a protocol. Authorized personnel can perform required updates and changes before the document is published.

Key Processes and Concepts

a. To provide the appropriate timeline defaults, the Review Track must be selected first.
b. Accept the field defaults, or modify the Create Timeline screen fields sequentially. The due dates and duration are interrelated and do not require data entry for each field.
c. Based on the previously selected Submission Type and the Review Track, the Review Stages fields are automatically populated with the recommended due date and duration of the activities related to the protocol. These recommended dates and durations can be changed.
d. The due dates and duration are presented as dependencies[12], and each functions in that manner. For example, if you change the Sign Off due date, the Resolve Comments and Incorporation of Changes due dates that follow are changed, in proportion to the Sign Off due date.

[12] You can change the default Durations and Due Dates. All of these elements are interrelated. If you change one and use the 'Update based on' function, all subsequent Durations and Due Dates (those lower in the hierarchy) are adjusted proportionately.

e. Docu-MART can automatically assist you in maintaining the balance and proportion of the review stages if a due date or duration is changed. After making a change, automatically update the others by selecting Due Date or Duration from the 'Updated based on' drop-down list, then click the **Go** button.
f. The number of days before the due date that an email is sent as reminder. There are separate 'remind' days for reviewers and the Site Coordinator/Protocol Specialist.
g. If the Submission Type is changed after the timeline has been created (but before publishing), a notification message displays about (potentially) losing timeline-related data.

Previous[13]*and***Next**[14]

Steps

1. Select the Review Track from the drop-down list to access the correct screen defaults.
2. In the Review Stages section, accept the default Duration and Planned Due Date or make changes by direct entry or the calendar function (for Planned Due Date).
3. From the 'Update based on' drop-down list, select the parameter that was changed: **Duration** or **Due Date**.
4. Click the **Go** button to update the Duration and Planned Due Date (if changes were made).
   - If the timeline is updated based on Duration, the system automatically calculates the due dates of all stages.
   - If the timeline is updated based on Planned Due Dates, the system automatically calculate the durations of all stages.

   The Total Duration calculates automatically when **Save** is clicked.

   Note: For CTEP Submissions, only the publish date displays. The timeline will be established by the Protocol Specialist using the View/Edit Timeline screen.

5. Enter the number of calendar days before the planned due date of the email reminder to be sent to the reviewers.

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[13] Before creating this timeline you must have completed the first two major steps in the publishing process: Upload Document and Assign Reviewers.

[14] You need to review the information and submit it for publishing. To get to that next screen, click the Next button or click the 'Confirm & Submit' disc in the left section of the Publish tab.

6. Enter the number of calendar days that an email reminder is to be sent to the Site Coordinator/Protocol Specialist *before* a reminder email is to be sent to the reviewers.
7. When completely finished, click the **Save or Completed & Next or Next button**.

Additional Features

After a step is marked as complete by clicking the **Completed and Next** button, a 'Reset to Not Completed' checkbox displays under the step name, featured in the Publish for Review box on the left. Clicking the checkbox, then clicking **Save** resets that step to ‘not complete’ and re-displays the **Completed & Next** button.

Create Timeline screen elements

Document identifiers appear automatically near the top of the screen.

The following elements are featured on the Create Timeline screen:

Field	How to Use	Description
Review Track	Drop-down list	Type of review track, such as Sequential or Collaborative.
Review Stages section:		
Publish and Notify	n/a	Date to start the Publishing process, defaults to current date.
Assign Reviewers & Timelines	Direct entry	Date reviewers and timelines are to be assigned.
Review, Comment & Reply by CTEP	Direct entry	Date all CTEP reviews are to be completed. *Note*: Discussions stop at this stage.
Submit Comments	Direct entry	Date the specific comment thread is to be submitted for internal and external review.

Review, Comment & Reply by Site	Direct entry	Date all site (internal) reviews are to be completed.
Resolve Comments	Direct entry	Date Site Lead is to accept or reject the comment thread.
Incorporate Comments	Direct entry	Date Site Coordinator is to incorporate each of the comment threads accepted by CTEP. *Note*: Site Coordinator might choose not to incorporate a comment thread.
Total Duration	n/a	Total number of calendar days for the review stages to be completed.
Remind Reviewers # day(s) before planned due date	Direct entry	Number of days before the actual due date that an email reminder is sent to *previously-assigned reviewers*.
Remind Protocol Specialist/Site Coordinator # day(s) before reminders are sent to reviewers	Direct entry	Number of days before the actual due date that an email reminder is sent to *the Site Coordinator*.
Auxiliary processing functions:		
Duration: (Calendar Days): Duration indicates the proposed allotted time for completing that specific process as expressed in business workdays.		
Planned Due Date: All Planned Due Dates can be edited using direct entry or by using the calendar selection icon. Changing a due date resets the dates featured lower in the hierarchy.		

Updated based on	Drop-down list and **GO** button	Refreshes fields in Stage Name section based on which changes to use -- Duration or Due Date.

Documents for Publishing

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This Documents Publishing screen is the major information and navigation screen for documents in the pre-published phase. It allows the Site Coordinator to see all Docu-MART authored documents and all non Docu-MART authored documents that the user uploaded.

Purpose

This screen is used to select an existing feature (or step) to edit, create a new submission, or begin the publishing process for a new document or new version of an existing document.

Key Processes and Concepts

These documents are in a variety of stages, as indicated by the round progress discs featured next to the local document version number listing. Unless sorted, they appear by local document version number in ascending order.

Disc Colors and Functions

A disc, or circle, is used to indicate the progress of the document:

Disc	Description	Used to indicate:
	White disc, blank	Non-navigational; required information on a previous screen was not entered. Return to that previous screen and complete required information, then proceed.

	White disc, partially filled	Some work has been done on that function, not marked as 'completed'
	Blue disc, raised	Function marked 'complete' but it can be edited if the publish date has not passed Therefore, it has not been published.
	Blue disc, flat	Function marked 'complete', it cannot be edited because the submission has been published.

> ***Note:*** Clicking the New Submission link begins the process of creating a new submission that retains data from the previous submission.

Submission Status Valid Values

- **Published**: The date assigned in Create Timeline has passed, the submission is published.
- **Saved for Publishing**: Complete, ready to be published.
- **In progress**: Not complete

Managing Documents for Publishing Records

- If the document has been submitted for publication, all discs in that row are filled in blue. A Create New Submission link appears below it.
- If a document version has been submitted for publishing but the Publish date has not yet occurred, it has not actually been published and changes can be made to supporting data (such as adding a reviewer). Make the change; then click **Save**. Any changes related to the timeline require the user to re-publish by deleting this submission and creating a new submission.
- If the document has been sent for publication, all discs in that row are filled in blue. A Create New Submission link appears below it.
- To delete a submission, check the checkbox next to it (under the 'Delete ?' column). Click **Save**.
- To make changes or additions once a document version is published, the user MUST create a new version.

Steps

To **create a new submission**, click the appropriate **Create New Submission** link. The screen then transfers to Assign Reviewers (Step 2).

To **publish a new document or new version of an existing document**, select the document type from the drop-down list), then click **Start**.

To **edit or complete an existing document version**, scroll to locate it on the list or use the Filter by function, then:

1. After locating the appropriate record, view the information in the row to determine the status of this document version. Click **All** to view all versions of this specific document. The title just above the row indicates if it is a Pre-submission or CTEP document.
2. Click the disk in the column for the appropriate action. If the disk is white, that particular action has not been completed. If it is blue, it has been completed and marked as such.

> ***Note***: If clicking on a disc does not display the screen, it means that the required information on previous screens has not been entered. Portions of the Docu-MART publishing process must occur sequentially.

Additional Screen Features

Filtering:

1. Click **Show Filter** to display the filtering fields.
2. Select the filtering (search) criteria, 'Document Type', 'NCI Document Number', 'Local Document Number', 'Phase', or 'Submission Type'.
3. Narrow the selection choices by entering a portion of the selection in the blank field to the left of the Open Reviews button. For example: Search by Local Document Number and enter 'CR' will display a list of all Local Document Numbers that start with 'CR', ending with anything will display.
4. Click the appropriate filtering button:
   - **Current Versions**: Lists all **current** document versions meeting the search criteria.

[15] This is the introductory screen to the Publishing function. To prepare for this process, know the location or be able to locate the relevant Docu-MART authored or non Docu-MART authored document.

[16] The next steps depend on the selections made on this screen.

- **All Versions**: List all document versions meeting the search criteria.

4. Scroll through this narrowed list if necessary.
5. Click **Hide Filter** to remove the filtering fields from view (optional).

Displaying all versions:

1. To see all versions, click **All Versions** without entering any search criteria.

Deleting a record:

1. To delete a record, click the **checkbox** to the right of the row.

   A Delete ? checkbox will not appear for a document version that has been sent for publication; it cannot be deleted.

Documents for Publishing screen elements

Document identifiers appear automatically near the top of the screen.

The following elements are featured on the Documents for Publishing screen:

Field	How to Use	Description
Publish new Document or Version?	Click **Start** button	Displays Upload Document -> Specify File Location screen, starting the process for uploading a new document or version.
Filter by (combination field)	Drop-down list, then direct entry	Options to *filter by*, either 'Document Type', 'NCI Document Number', 'Local Document Number', 'Phase', or 'Submission Type'
Document Identifiers - Column Headings		
Document Type (Doc. Type)	none	Category, or type, that describes this document.

• Local Document Number • NCI Document Number	none	Identifying code for this document, as determined by its initiating group Unique identifier for a document. If the document is submitted by a group, the group document number is used. If not, the identifier is system-generated.
• Local Version • Version Date	none	Numeric identifier for this version: assigned by the initiating group. Date current version was created.
Docu-MART Authored	none	(Docu-MART logo) indicates that the document is Docu-MART authored.
• Submission Type • Review Status	none	Category or type of this submission, such as Pre-Submission[17] or CTEP Submission[18]. Current status of review, Open or Closed.
• Submission Status • Submission Date	none	Current status of the submission. Valid values are Published, Saved for Publishing, and In Progress. Date status was changed to the current submission status.

Publishing Process Steps - Column Headings

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[17] When the document is finished it will be ready for internal reviewbefore it is submitted to CTEP.

[18] When the document is finished it will be CTEP-ready, and may or may not be submitted for internal review.

Upload Document	Click disc (circle)	Mechanism to transfer directly to the Upload Document screens for the selected document.
Assign Reviewers	Click disc (circle)	Mechanism to transfer directly to the Assign Reviewers screen for the selected document.
Create Timeline	Click disc (circle)	Mechanism to transfer directly to the Create Timeline screen for the selected document.
Confirm & Save	Click disc (circle)	Mechanism to transfer directly to the Confirm & Save screen for the selected document.
Delete	Click checkbox	Selecting this will delete the document from the list when the Save button is clicked. Available for 'works-in-progress' only.

First Occurrence - Adding a User Role

If a user does not have a Docu-MART role and is selected to be added to the protocol, it will show the Review and Lead Reviewer role options for this user, with the Reviewer role option checked as the default. If necessary, the role can be changed by checking the Lead Reviewer option. This is applicable to any user with any IAM (Identify and Access Management) account status except ‘denied’.

Note: If the user is linked to an IAM account but does not yet have an assigned role in Docu-MART, the Reviewer role will be assigned back into IAM after the information is saved within the Docu-MART application.

After saving, the reviewer roles for this user are then assigned to Docu-MART for the current protocol and for future use.

Progress Bar

On the left of the screen is a list of the four major Publishing functions: Upload Document, Assign Reviewers, Create Timeline, and Confirm and Save. On specific occasions, sub-headings appear under the Upload Document title.

A disc, or circle, is used to indicate the progress of the document:

Disc	Description	Used to indicate:
	White disc, blank	No work has been done on that function
	White disc, partially filled	Some work has been done on that function, not marked as 'completed'
	Blue disc, raised	Function marked 'complete' but it can be edited.
	Blue disc, flat	Function marked 'complete', it cannot be edited.

Search and Select: Agents

1. Scroll to the appropriate NSC code or name, or use the Search by function.
   - To use the Search by function, select the search criteria, NSC (code) or Name. This function is found in the Search/Filter Criteria section of the screen.
   - You can narrow the selection choices by entering a portion of the selection in the blank field to the left of the **Go** button. For example, if you search by NSC and enter '31', a list of all NSC codes that start with '31', ending with any numbers, displays after you click **Go.** In the same manner, if you search by Name and enter 'Pi', all Agents that start with the letters Pi display in alphabetical order.
2. Click the checkbox for the appropriate NSC code(s) to select. You can choose multiple agents on this screen.
3. Click **Add Selected** to copy the agent to the Selected Agents section.

Note: To remove a selection, click that Remove checkbox (in the Selected Agents section, then click **Remove Selected.** You can delete multiple agents.

4. Click **Done**.

If it is necessary to add agents to the selection list, contact **info@ctep.nci.nih.gov**.

Search and Select: Diseases

1. Select the 'Category' from the drop-down list.
2. Select the 'Subcategory' from the drop-down list.

   The subcategories available for selection depend upon the chosen category.

3. Select the Search by function, select the search criteria, Reporting MedDRA Code or Name.
   - You can narrow the selection choices by entering a portion of the selection in the blank field to the left of the **Go** button. For example, if you search by Reporting MedDRA Code and enter '800', a list of all of the codes that start with '800', ending with any numbers, displays after you click Go. In the same way, if you search by Name and enter 'Ex', all Diseases starting with the letters Ex display in alphabetical order.
4. Click the appropriate Reporting MedDRA Code(s) to select. You can choose multiple diseases on this screen.
5. Click **Add Selected** to copy the disease to the Selected Diseases section.

Note: To remove a selection, click that Remove checkbox (in the Selected Diseases section), then click R**emove Selected**. You can delete multiple diseases.

6. Click **Done**.

If it is necessary to add diseases to the selection list, contact **info@ctep.nci.nih.gov**.

Search and Select: Document Number

The Document Numbers available for selection are specific to your organization.

1. Scroll to the appropriate NCI Document Number name or use the Search by function.
   - To use the Search by function, select the initial portion of the NCI Document Number to use for the search. For example, if you enter '60' after selecting and click **Go,** all documents starting with the numbers '60', ending in anything, will display.
   - Scroll through this narrowed list if necessary.
2. Click the appropriate NCI Document Number link to select.

Search and Select: Reviewers

The reviewers available for selection are specific to your organization.

1. Select your 'Organization' from the drop-down list (in the Search/Filter Criteria section).
2. Scroll to the appropriate name or use the Search by function.
   a. To use the Search by function, select the portion of the name to use for the search: Last Name or First Name.
   b. Enter the appropriate name (based on your selection) in the blank field to the left of the **Go** button. You also can enter a portion of the name. For example, if you enter 'Mi' after selecting 'Last Name' and clicking **Go**, reviewers with last names such as Miller and Middleton display.
3. Click the appropriate name(s) to select.
4. Click **Add Selected**.

Note: To remove a selection, click the Remove checkbox (in the Selected Reviewers section), then click R**emove Selected**. You can delete multiple reviewers.

5. Click **Done.**

Specify Document Profile

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

The contents of these screen fields depend on which document type you selected on the previous screen, Specify Non Docu-MART Document Version Type. If you selected 'New Document', the fields will be blank. If you select 'New Version for an existing Document', the fields will be completed with the contents of the linked document. If you link to a Concept or LOI, some fields are also completed automatically.

Purpose

The Specify Document Profile screen provides the mechanism for creating the basic structure that contains the major identifying information.

Key Processes and Concepts

The screen elements selected provide the framework for the document's text.

- If you linked this document to an existing document or to an LOI/Concept, these screen elements pre-populate this screen. You can change or add to the existing text
- If you chose to create a new document, the fields are blank.

When there is a set number of appropriate selections, as with the selection of Document Type or Phase, the appropriate drop-down lists are available. Information that is document-specific or customized for you site is entered directly into the appropriate field.

You can add multiple agents and multiple diseases to this document:

a. By clicking the Agents **Add** button, you can select Agents to associate with this document.
b. By clicking the Diseases **Add** button, you can select Diseases to associate with this document.

Note: Click the Select All link to mark all Agents or all Diseases as ready for delete, then click the **Clear All** link to remove these marks.

Previous[19] *and* **Next**[20]

Steps

The following directions are for blank fields, but the concept is the same for adding to or changing existing information.

1. Complete the screen fields by the appropriate method; direct entry or using the drop-down list. For the Local Version Date, click the calendar icon to the right of the field, then click the exact date.
2. Add an Agent by clicking on the **Agent** button to display the Agent window. Click on the checkbox to select the appropriate NSC number(s).
3. Click **Add selected** to move selected agents to the Selected Agents block.

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[19] On the Specify Non Docu-MART Document Version Type screen, you must have specified the non Docu-MART document to upload, then selected the document type--New, or linked to an existing document or LOI/Concept.

[20] You must organize the structure of the sections for this non Docu-MART authored document. To get to that next screen, click the Next button or click the Specify Document Sections disc in the left section of the Publish tab.

4. Click **Done** to navigate to the Upload Document -> Specify Document Profile screen.
5. Add a Disease by clicking on the **Disease** button to display the Disease window. Select the category and subcategory from the drop-down lists and choose the 'Search By' option, Reporting MedDRA Code or Name. Click the **Go** button, then click on the checkbox for appropriate MedDRA code(s).
6. Click **Add selected** to move selected agents to the Selected Agents block.
7. Click **Done** to navigate to the Upload Document -> Specify Document Profile screen.
8. Click the appropriate button, **Save** or **Completed** & **Next,** or **Next**.

Additional Features

After a step is marked as complete by clicking the **Completed and Next** button, a Reset to Not Completed checkbox displays under the step name, featured in the Publish for Review box on the left. Clicking the checkbox, then clicking **Save** resets that step to 'not complete' and re-displays the **Completed & Next** button.

Specify Document Profile screen elements

The following elements are featured on the Specify Document Profile screen:

Field	How to Use	Description
Local Document #	Direct Entry	Identifying code for this document, as determined by its initiating group
Local Version #	Direct Entry	Numeric identifier for this version, as assigned by the initiating group.
Title	Direct Entry	Complete name of this document.
Lead Organization	Drop-down list	Name of the group that starts or is responsible for this document.
Document Type	Drop-down	Category, or type, that describes

	list	this document.
Phase	Drop-down list	Stage, or phase, related to this document, Phase I - IV. Defaults to Phase III.
Local Version Date	Direct entry or Calendar icon	Date to be associated with this local version, defaults to current date. *Note:* If you enter a date that is earlier than this date in an existing version, a warning message displays.
Select All	Click link	*Performs the appropriate action--selects all associated Agents or selects all associated Diseases*
Clear All	Click link	*Performs the appropriate action--clears all associated Agents or clears all associated Diseases*
Agents	see Agents	
Diseases	see Diseases	
Delete ?	Click to remove row from the screen after saving or progressing.	

Specify Document Sections

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

A non Docu-MART authored document must have sections that are compatible to those that were authored in Docu-MART. This screen displays the section names and the associated and section numbers (positions) from the current default template for your organization.

Purpose

The Specify Document Profile screen is used to specify and select the document sections to give the text of a non Docu-MART authored document an organized, recognizable structure for use in Review and Commenting procedures.

Key Processes and Concepts

By deleting, adding, moving, or changing section names, you provide a organized structure that allows efficient reviewing and commenting. In other words, you want to associate the contents of the non Docu-MART authored document as closely as possible with section headings and structure of a Docu-MART authored document. Each screen element is designed for that purposed.

> ***Note***: The Add Subsection function is designed to insert an automatically number subsection immediately below the select 'parent' section.

Essentially, the main purpose of this screen is to create some degree of standardization between Docu-MART Authored documents and non Docu-MART authored documents. The end result is documents that are easier to manage because of consistency and easier to review and comment because information is identified properly in known terms.

> When adding section headings, you can add equivalent sections (such as 1, 2, or 3), a subsection to a section (2.1 to 2), an equivalent subsection to a subsection (2.2 to 2.1), or a 'lesser' subsection to a subsection (2.3 1 to 2.3).

Previous[21]*and***Next**[22]

Steps

1. Accept the default template or select another one from the 'Based On template' drop-down list.

   Note: If the existing template is changed, a warning message displays stating that all existing sections will be deleted, to be

[21] On the Specify Profile Document screen, you must have entered the basic identifying information (local document number, title, phase, and so on) for this specific document version.

[22] You assign the reviewers for this document that has finished the uploading process, thus beginning the final three Publishing steps. To get to that screen, click the Next button or click the 'Assign Reviewers' disc in the left section of the Publish tab.

replaced by those sections in the new template. This information will be saved automatically. No other information is affected, just the section numbers and headings.

2. To delete any section, click the checkbox on the left. You can delete more than one section at a time. These sections will be deleted when you click **Save**, **Completed & Next,** or **Next**.
3. To add a section, you must perform two actions—add a section row, then enter the section name.
   a. Select where you want to add a section, then click on the appropriate direction arrow. You can click on the actual Above arrow to add a blank section row above the existing one, or click on the Down arrow to add one below. Notice that the sections renumber automatically, and the one that you just added has the same heading level as the existing section.
   b. In the blank Section Name field, enter the name of this new section.
4. To add a subsection, you must perform two actions—add a subsection row, then enter the its name.
   a. Select which section is to receive the subsection, then click on the **Add Subsection** curved arrow icon.
   b. In the blank Section Name field, enter the name of this new subsection.
5. Click the appropriate button, **Save** or **Complete & Next**.

Additional Features

After a step is marked as complete by clicking the **Completed and Next** button, a Reset to Not Completed checkbox displays under the step name, featured in the Publish for Review box on the left. Clicking the checkbox, then clicking **Save** resets that step to 'not complete' and re-displays the **Completed & Next** button.

Specify Document Sections screen elements

Document identifiers appear automatically near the top of the screen.

Most screen activities affect the automatic renumbering[23] of the sections.

[23] Moving or adding sections automatically renumbers each heading. For example, if you move section 6.1, 6.2 then replaces 6.1 and 6.3 moves up to 6.2. Also, removing section 4 would move section 5 to that position (and so on).

The following elements are featured on the Specify Document Sections screen:

Field	How to Use	Description
Delete Add Above Add Below	Click checkbox Click up arrow Click down arrow	Removes the section row when Save or Completed and Next buttons are clicked. Inserts containing the click 'above' arrow. Inserts a blank row below the row containing the click 'above' arrow.
Add Subsection	Click arrow, then click checkbox	Inserts a subsection to the selected 'parent' section.
Move From	Click checkbox	Indicates which section row is to be moved.
Move To	Click checkbox	Indicates the target (or end result) of the section row to be moved.
Position	none	Used in conjunction with the 'Move To' function, it identifies the reassigned section number.
Section Name	Direct Entry	The actual section names, they default to those in the template.

Specify File Location

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	StepsDocu-MART Authored-	Steps-Non Docu-MART Authored

Introduction

A document must be selected before it can be uploaded. A document that was authored using Docu-MART's Authoring Tool has only one step here, and that is to be selected. However, with a non Docu-MART authored document, this is the initial step for bringing existing text into Docu-MART for later use in the Review and Commenting process.

Purpose

The Specify File Location screen is used to select the document to be uploaded and processed.

Key Processes and Concepts

- Enter the file name and path in the File Name field or use the Browse function to complete the field.
- The document file can be changed without returning to the previous screen by using the Browse function associated with the File name field.
- The Document Type displays near the screen title.

Note: Sometimes changes to this screen, such as selecting a new Document File, are not immediately apparent until progressing to the next screen. The Additional Attachments button works like a 'Refresh' function and updates the screen display.

- After clicking **Continue**, the subsequent actions depend on the type of document being uploaded: **.dxw** for a Docu-MART authored document, or **.pdf** or **Word** for a non Docu-MART authored document.

  A related application download might be required at some point.

At this stage, there are major functional differences between a Docu-MART authored document and a non Docu-MART authored document:

Docu-MART Authored Document

- A **Docu-MART authored document** was created using Docu-MART's Authoring Tool. It has already been through the preliminary steps of assigning a version type, specifying the document profile (which includes assigning Agents and Diseases), and specifying the appropriate sections to appear in the completed document.
- After choosing a Docu-MART authored document, the Assign Reviewers screen automatically displays.

Non Docu-MART Authored Document

- A **non Docu-MART authored document** has not been through these preliminary steps. Therefore, four processes within three sequential screens are provided to allow these steps to be performed.
- After selecting a non Docu-MART authored document, the Specify File Location screen changes to contain additional data elements related to attachments.
- The three subsequent screens, Specify Non Docu-MART Document Version Type, Specify Document Profile, and Specify Document Sections display automatically and must be completed before transferring to the Assign Reviewers screen.
- Attached files can be used to support the information in a Docu-MART document. A PSW file and/or a Change Memo File can be attached by using the Browse function associated with that field. These attachments will then be associated with this document throughout its Docu-MART life-cycle. Clicking the **Additional Attachments** button displays more field/browse combinations that can be used to associate more files. 'Delete?' boxes indicate if files can be deleted.

Previous[24] *and* **Next**[25]

Steps - Docu-MART Authored

1. Enter the path and name of the appropriate file in the File Name field or use the Browse button to locate the file. This Browse function works in the standard manner used in traditional applications.
2. Click the **Continue** button.

Steps - Non Docu-MART Authored

These steps are in addition to the steps performed for a Docu-MART Authored document.

1. To attach a PSW file or a Change Memo file (or both), use the entry box/browse button combination field to the right of each attachment type to access the file.

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[24] You must have created a 'Docu-MART ready' document, by using Docu-MART's authoring function or by creating a relevant Word, Word Perfect, or .pdf document.

[25] With a Docu-MART authored document, your next step is to Assign Reviewers (click Next or the Assign Reviewers disc, left of screen.. With a non Docu-MART authored document, you must complete 3 more 'upload' steps. The correct screen displays automatically.

2. Click the **Additional Attachments** button as often as necessary to display more selection/browse rows that allow miscellaneous documents to be attached.
3. Click the **Continue** button.

Additional Features

1. Click the 'Remove?' checkbox to delete the associated entry if desired. The file will be deleted when the file is saved or after transferring to another screen (optional).

Specify Non Docu-MART Document Version

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Screen elements

Introduction

Unlike a Docu-MART authored document, a Non Docu-MART Document is not automatically structured and formatted in accordance with the requirements of subsequent Docu-MART activities. This screen is used to make such a document ready for the complete Docu-MART process.

Purpose

The Specify Non Docu-MART Document Version Type screen is used to develop the basic structure of the new document.

Key Processes and Concepts

The selection type indicates what information is brought into the new document.

If you choose:

- **Create a New Document**; you are essentially starting with a blank document, with no existing text.
- **Create New Version of an Existing Document**; you then link[26] to one of your existing document and copy relevant information into the relevant fields of the subsequent screens for creating this new version. You can then add to of edit this text to justify the need for this 'new version'.

[26] Clicking on this radio button displays the 'Link to Document' option, where you click on the icon to display the Search and Select: Document Number window.

The available selections are the latest versions of documents you created.

- **Link to LOI,** you then link to an existing Letter of Intent. Relevant supporting information from the LOI will then automatically populate specific fields on the subsequent screens. The benefit of this selection is that you decrease data entry by importing pertinent data from existing materials.

The available selections are the approved LOIs from PATS.

- **Link to Concept,** you then link to an existing Concept paper. Relevant supporting information from the Concept will then automatically populate specific fields on the subsequent screens. The benefit of this selection is that you decrease data entry by importing pertinent data from existing materials.

The available selections are the approved Concepts from PATS.

Previous[27] *and* **Next**[28]

Steps

1. Click on the radio button to the left of the appropriate selection that defines this current document.

   If you choose **Create a New Document**:

   a. Click the **Continue** button.

   If you choose **Create a New Version for an Existing Document**, the Link to Existing Version field displays.

   a. Click on the **List of Values** icon to the right of the field to display the selection of documents.
   b. Select the appropriate document using Search and Select: Document Number.
   c. When finished, click the **Continue** button.

   If you choose **Select LOI**, the Link to LOI field appears:

   a. Click on the **List of Values** icon to the right of the field to display the selection of documents.

[27] On the Specify File Location screen, you must have entered or selected the non Docu-MART Authored document to be uploaded. This document can be in .pdf, Word, or Word Perfect form.

[28] You specify the document profile, by adding or editing identifying and supporting text. To get to that next screen, click the Next button or click the Specify Document Profile disc in the left section of the Publish tab.

b. Select the appropriate document using Search and Select: Document Number.
c. When finished, click the **Continue** button.

If you choose **Select Concept**, the Link to Concept field appears:

a. Click on the **List of Values** icon to the right of the field to display the selection of documents.
b. Select the appropriate document using Search and Select: Document Number.
c. When finished, click the **Continue** button.

Specify Non Docu-MART Document Version Type screen elements

Document identifiers appear automatically near the top of the screen.

The following elements are featured on the Specify Non Docu-MART Document Version Type screen:

Field	How to Use	Description
File Type	none	Mode or type of file to be uploaded; Docu-MART Authored or Non Docu-MART Authored.
File Name	none	Name and file extension of the file to be uploaded. ' Docu-MART authored' has .dxw extension. Note: For DXW application requirements or information, contact: ncictephelp@ctep.nci.nih.gov
Create New Document	Click radio button	Indicates that a new document is to be created, no linking necessary.
Create New Version for an Existing Document	Click radio button	Indicates that a new document is to be created and linked to an existing document.
Link to LOI	Click radio	Method to display the Search and Select: Document Number

	button	window, used to link to an LOI.
Link to Concept	Click radio button	Method to display the Search and Select: Document Number window, used to link to a concept.

Unlisted Reviewers: Edit Button

After clicking on the Edit button to the left of the unlisted agent's name, the Unlisted Reviewers window opens for editing.

1. Change, add, or delete the relevant screen information.
2. Click **OK** to save the edits and return to the Assign Reviewers screen.

   This unlisted reviewer record is now changed for the current document.

   Optional:

   1. To link to the Assign Reviewers screen while in this Edit process, click the **Link to Docu-MART account** button. The Search and Select Reviewers window displays.
   2. Click the appropriate name link on the Unlisted Reviewers screen to transfer automatically to the Reviewers screen.

   Note: Use of the **Link to Docu-MART account** button is based on authorization.

Application Downloads

For DXW application requirements or information, contact: ncictephelp@ctep.nci.nih.gov.

For PDF or FlashPlayer application requirements or information, contact: http://www.adobe.com/ and select Downloads.

For MS Word application requirements or information, contact: http://www.microsoft.com/ and select Resources, then Downloads.

For Word Perfect application requirements or information, contact: http://www.corel.com/.

Dates and Durations

On the first visit to this timeline screen, that is, you have not previously assigned any dates or durations, the dates will automatically be assigned according to business days but in accordance with the durations.

Here is a basic example: Based on the template, a duration is set for 3 days, with day 3 falling on a Sunday. The duration will then automatically be reset to 4 days on the timeline screen since the durations are expressed in working days. This is without any user intervention.

However, after there is any user intervention (any action on the screen, such as date or duration changes) all dates/durations will be expressed in calendar, not working, days. For example, if the duration is set at 4 days on a Thursday, a warning message displays stating that the due date falls on a Sunday. The option is then presented to keep the Sunday due date or change it to another day.

Selecting an NCI Document version

When the Protocol Specialist logs into this View/Edit Reviewers screen for the first time, his or her name automatically populates this screen.

An NCI version is also automatically linked, but the Protocol Specialist must confirm that the version is the correct one or select another one. After the NCI version is confirmed, the PATS reviewers are then automatically assigned.

If the Protocol Specialist accepts the NCI Document Version:

1. Click **Confirm**. The default NCI Document Version is confirmed and the PATS reviewers are assigned.

   Note: The reviewers from PATS are assigned after the **Confirm** button is clicked. After clicking **Save**, the NCI version is saved in the database.

If the Protocol Specialist does not accept the NCI Document Version:

1. Click **Edit & Confirm**. The NCI Document Version list displays, containing all available versions from PATS.
2. Choose the appropriate version by clicking on the associated radio button.

3. Click **Confirm**. The selected NCI Document Version is confirmed and the PATS reviewers remain unchanged. Use the **Edit** or **Add** functions to make changes to the reviewers.

View/Edit Reviewers

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This function allows reviewers assigned in Publishing module to be changed or viewed directly from the Tasks tab. The ability to view or edit the reviewer information is based on assigned roles.

Purpose

The View/Edit Reviewers screen is used to change or review the list of reviewers for the document.

Key Processes and Concepts

- You can change a reviewer's role for this document by checking another selection in the Role column. Only appropriate roles display, based on Docu-MART application rules.
- A CTEP Submission can be linked to an NCI Document Number, which then automatically populates the latest CTEP version (as well as all reviewers).
- The Add function for adding a reviewer works from a list of the site-specific available reviewers. If necessary, users can switch to a site that is not their own, to access those additional reviewers. After selecting a reviewer, the role must be assigned to that reviewer.
- The Add Unlisted Reviewer function is used to add other reviewers to this document that are not currently listed in the available reviewers. The record can be saved for future use. This unlisted reviewer record can also be edited.
- The Add Distribution List function (available to CTEP reviewers) lets you select a distribution list (for example, a department or group of reviewers) for use as an unlisted reviewer.
- The four 'Authorize to Change' functions are essentially Yes or No mechanisms.

Steps

Adding a reviewer:

1. Click the **Add** button. The Reviewers screen displays.

   The reviewers available for selection are specific to your organization, and are featured in the bottom half of the screen.

2. From the drop-down list, select the 'Organization' to which the Reviewer belongs.
3. Scroll to the appropriate name or use the Search Filter Criteria.
   a. To use the Search Filter Criteria, select the portion of the name to use for the search: Last Name, First Name, Account Name, or Email.
   b. Enter the appropriate name (based on your selection) in the blank field to the left of the **Go** button. You also can enter a portion of the name. For example, if you enter 'Mi' after selecting 'Last Name' and clicking **Go**, reviewers with last names such as Miller and Middleton display.
4. Click the appropriate name(s) to select.
5. Click **Add Selected**. That reviewer's record then transfers to the top section, 'Selected Reviewers'.

   > Note: To remove a selection, click that checkbox (as featured in the lower section), then click Remove Selected. You can delete multiple reviewers.

6. Click **Done**.

For the Protocol Specialist only

If this **is** the first time this View/Edit Reviewers screen is accessed:

1. Click **Save** or **Next**.
2. On the View/Edit Timeline screen click **Notify** to publish the tasks and send the appropriate emails.

If this i**s not** the first time this View/Edit Reviewers screen is accessed, click **Save & Notify.**

Adding a reviewer not on the list:

1. Click the **Add** button. The Reviewers screen displays.
2. Click the **Add Unlisted Reviewer** button. The Unlisted Reviewers screen displays.
3. By direct entry, complete all mandatory fields, noted by an asterisk (*) and optional fields on the screen.
4. In the Organization field, indicate the Organization to which the Reviewer belongs.
5. Select **Yes** to request an account for the Unlisted Reviewer to access the Docu-MART system.

Once their account is activated and approved, they will be able to login to Docu-MART and complete their review tasks.

6. Select **No**, if this Unlisted Reviewer does not require an account to access the Docu-MART system.

Their review tasks will be delegated to the Site Coordinator/Protocol Specialist.

7. Click **OK** to save the new reviewer record and return to the Reviewers screen.

This Unlisted Reviewer record is now attached to the current document. Now, on the Reviewers screen, the newly added name will be shown.

1. Click **ADD SELECTED** on the newly added name.

2. Notice that the reviewers' record is now appearing in the top section labeled "Selected Reviewers'.

3. Then, click **DONE**.

You are now returned to the View/Edit Reviewers screen.

4. Click **SAVE** to link the Unlisted Reviewer to the current document.

Changing or adding authorization levels:

1. Click the appropriate checkbox under the 'Authorize to Change' columns:
   - 'Timeline' allows this reviewer to manage timelines.
   - 'Reviewers' gives this reviewer the ability to add other reviewers.
   - 'Facilitated' indicates that this reviewer cannot submit comments directly; they first must be evaluated by the Lead Reviewer.
   - 'Delegated' indicates that this reviewer grants the Site Coordinator/Protocol Specialist the right to enter, add, and change the review text

   See the View/Edit Reviewers screen elements for the complete column names and for more information about these authorization levels.

2. When finished, click the **Save and Notify** button, all changes and additions are saved to the database and email notifications about the edits are sent.

Additional Features

The first time this screen is used to link to PATS (for CTEP submissions), a Save button displays. Click **Save** after linking to PATS, then click **Save and Notify** when finished.

Confirm NCI Document version:

1. An NCI Document version must be selected/confirmed on this screen.

Editing a reviewer not on the list:

1. Click the **Edit** button to the left of the unlisted reviewer's name. The Unlisted Reviewers window opens for editing.
2. Change, add, or delete the relevant screen information.
3. Click **OK** to save the edits and return to the View/Edit Reviewers screen. This Unlisted Reviewer record is now changed for the current document.

You need to click SAVE on the View / Edit Reviewers screen to save the changes to the newly added Reviewer.

Optional:

1. To link to an existing Docu-MART account, click the Link to Docu-MART account button. The Link to Docu-MART account window displays.

Note: Use of the Link to Docu-MART account button is based on authorization.

2. Enter the appropriate name in the field to see a list of existing accounts.
3. Click on the appropriate account.
4. Then, you are returned to the Reviewers window.

Deleting a reviewer:

1. In the Delete column, click the checkbox to the left of the appropriate reviewer. That reviewer row disappears after clicking **Save**.

Filtering (Search/Filter Criteria):

1. On the Reviewers window, choose the filtering criteria to be used in the search. These filtering options can be used singularly or in combination.

- **First Name**: Enter the complete first name or a portion of the first name. For example, if you know that the first name is Steven or Stephen but are not certain of the exact spelling, enter 'Ste'.
- **Last Name**: Enter the complete last name or a portion of the last name. For example, if you know that the last name is Smith or Smythe but are not certain of the exact spelling, enter 'Sm'. This field can also be left blank but it is not recommended.
- Select the appropriate **Organization** from the drop-down list. Select 'All' if the organization is unknown or to include every organization in the search.

2. Click **Go** to display the names meeting all of the search criteria.

Rules for CTEP Submission

There are specific guidelines and rules for the use of the View/Edit Reviewers function for CTEP submission.

View/Edit Reviewers screen elements

Document identifiers[29] appear automatically near the top of the screen. These are read-only values from the document profile.

The following elements are featured on the View/Edit Reviewers screen:

Field	How to Use	Description
Submission Type	Drop-down list	Category or type of this submission, such as Pre-Submission[30] or CTEP Submission[31].
Site Reviewing Team **or** CTEP Reviewing Team	Click **Add** button	Clicking this button displays the Reviewers screen.

[29] NCI Document number, Document Type (P for Protocol, LOI for Letter of Intent, C for Concept) Local Document number, Version (Date), Submission Type (Pre-submission, CTEP, etc), and Roles. A Title link accesses additional document-related information.

[30] When the document is finished it will be ready for internal reviewbefore it is submitted to CTEP.

[31] When the document is finished it will be CTEP-ready, and may or may not be submitted for internal review.

Edit (button)	Click button	Clicking this link display the Unlisted Reviewers edit window. This Edit button only appears after 'Add' has been used.
Reviewer section:		
Delete?	Click to select	Indicates that this reviewer is to be removed from the screen when the **Save** button is clicked.
Reviewer	none	Full name of reviewer selected from the list of available reviewers.
Role	Drop-down list	Function of the reviewer for this protocol; Lead Reviewer, Reviewer, or Site Coordinator.
Authorize to Change section		
Timelines	Click to select	This reviewer can edit document timelines.
Reviewers	Click to select	This reviewer can assign other reviewers to this document.
Facilitated (Cannot submit comments directly to external Reviewers)	Click to select	The comments must be assessed by the Lead Reviewer before it is distributed. This reviewer cannot submit directly.
Delegated (Task performed by Site Coordinator/Protocol Specialist)	Click to select	This reviewer grants the Site Coordinator/Protocol Specialist the right to enter, add, and change the reviewer's comments (in draft mode).

View/Edit Timelines

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This function manages the timeline that was created using the Publishing module directly from the Tasks tab. Viewing or editing the timeline information is based on assigned roles. The ability to perform these actions is also affected by a stage task subsequently checked as 'complete' on the Review and Commenting screen.

Additionally, this function provides email notification[32] to all reviewers concerning changes made in the timeline.

Purpose

The View/Edit Timelines screen is used to change or review specific timeline information and to notify the reviewers of any changes.

Key Processes and Concepts

- The ability to change dates depends of the level of authorization, and if a stage task has been checked as 'complete' on the Review and Commenting screen.
- If Resolve Comments is complete, no updates can be performed on previous review stages.
- The dates that can be changed have data entry boxes in the Duration and Due Date columns.
- Accept the field defaults, or modify the View/Edit Timeline screen fields sequentially. The due dates and duration are interrelated and do not require data entry for each field.
- Based on the previously selected Submission Type and the Review Track, the Review Stages fields are automatically populated with the recommended due date and duration of the activities related to the protocol. These recommended dates and durations can be changed.
- Due dates and duration are presented as dependencies[33], and each functions in that manner. For example, if you change the

[32] For all document types other than Pre-submission, clicking the Notify button after completing all changes sends an email containing the updated information.

Resolve Comments due date, the Incorporate Comments due date that follows is changed, in proportion to the Resolve Comments due date.

- Docu-MART can automatically assist you in maintaining the balance and proportion of the review stages if a due date or duration is changed. After making a change, automatically update the others by selecting Due Date or Duration from the 'Updated based on'.drop-down list, then click the **Go** button.
- Functions appear on this screen that allow you to select the number of days before the due date that an email is sent as reminder. There are separate reminding functions for reviewers and the Site Coordinator.
- There are two reminder fields. The Site Coordinator reminder will almost always be set at least one day (and often more) before the general reminder.
- A view-only Stage Completed checkmark displays when all stage tasks for that submission are indicated as complete within the Review and Commenting process.
- A Close Review Early data entry window only displays after Close Review Early? is checked. This information remains associated with the document.

Planned and Actual Due Dates/Updating Timelines

- If the previous stage is complete, the current stage's **planned end date** must be greater than or equal to the previous stage's **actual completed date**.
- If the previous stage is not complete, the current stage's **planned due date** must be greater than or equal to the previous stage's **planned due date**.

  The total duration is updated automatically as changes are made on this screen.

Steps

1. In the Review Stages section, make changes to the appropriate timeline fields by direct entry or the calendar function (for Due Dates).
2. From the 'Update based on' drop-down list, select the parameter you just changed—Duration or Due Date.

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[33] The default Durations and Due Dates can be changed. All of these elements are interrelated. If one is changed and the 'Update based on' function is used, all subsequent Durations and Due Dates (those lower in the hierarchy) are adjusted proportionately.

   - If the timeline is updated based on **Duration**, the system automatically calculates the **due dates** of all stages.
   - If the timeline is updated based on **Due Dates**, the system automatically calculates the **durations** of all stages.
3. Complete the Reminder Fields:
   - General reminder (Remind X number of day(s) before the due date): Accept the default, or change that number to indicate how many days before the due date a reminder email is to be distributed to all relevant personnel. The minimum value allowed is 0 days.
   - Indicate how many days in advance a Site Coordinator/Protocol Specialist has to edit outgoing email messages for this document. The minimum value allowed is 1 day.
4. Click the **Go** button to update subsequent Durations and Due Dates.
5. For all submission types other than Pre-submission, click the **Notify** button after completing all changes to send email containing the updated information to the appropriate reviewers.

Additional Features

Close Review Early

A review can be closed earlier than originally planned.

1. Click the **Close Review Early?** checkbox. The Early Closure Reason entry box displays, as does the Early Closure date with today's date.
2. Enter explanatory information about the reason this document review is being closed.
3. Click **Close Review** to end this review process and send an automatic email notification to relevant personnel. ***Note***: There is a prompt requesting confirmation for the early closure.

Histories

- Clicking the **Stage Dates History** button displays the history of all activity, per date and per task.
- After a document is marked as complete, the date of completion is featured as a link in the Actual Completed Date column. Clicking the **link** displays the history of everyone's activity on that date for the specific submission.

View/Edit Timelines screen elements

Document identifiers[34] appear automatically near the top of the screen. These are read-only values from the document profile.

The following elements are featured on the View/Edit Timeline screen:

Field	How to Use	Description
Review Track	Drop-down list	Type of review track, such as Sequential or Collaborative.
Review Stages section:		
Publish and Notify	n/a	Date to start the Publishing process, populated based on values set in the Create Timeline function.
Assign Reviewers & Timelines	Direct entry	Date reviewers and timelines are to be assigned.
Review, Comment & Reply by CTEP	Direct entry	Date all CTEP reviews are to be completed. *Note*: Discussions stop at this stage.
Submit Comments	Direct entry	Date the specific comment thread is to be submitted for internal and external review.
Review, Comment & Reply by Site	Direct entry	Date all site (internal) reviews are to be completed.
Resolve Comments	Direct entry	Date Site Lead is to accept or reject the comment thread.

[34] NCI Document number, Document Type (P for Protocol, LOI for Letter of Intent, C for Concept) Local Document number, Version (Date), Submission Type (Pre-submission, CTEP, etc), and Roles. A Title link accesses additional document-related information.

Incorporate Comments	Direct entry	Date Site Coordinator is to incorporate each of the comment threads accepted by CTEP. *Note*: Site Coordinator might choose not to incorporate a comment thread.
Remind # days before the due date	Direct entry	Number of days before the actual due date that an email reminder is sent to *previously-assigned reviewers*.
Remind # days before the due date to Site Coordinator	Direct entry	Number of days before the actual due date that an email reminder is sent to *the Site Coordinator*.
Auxiliary processing functions:		
Duration: (Calendar Days): Duration indicates the proposed allotted time for completing that specific process as expressed in business workdays.		
Due Dates: All Due Dates can be edited using direct entry or by using the calendar selection icon. Changing a due date resets the dates featured lower in the hierarchy. **Planned Due date** is the target date established at the time the document is being prepared for publication. **Actual Due Date** is the date the document was actually published.		
Update based on	Drop-down list and **GO** button	Refreshes fields in Stage Name section based on which changes to use -- Duration or Due Date.
Close Review Early ?	Click checkbox	Indicates that the review is to be closed before the projected review completion date. Two fields appear after checkbox is clicked:

Early Closure Date	n/a	Current date, date of review closure.
Early Closure Reason	Direct entry	Details about the reasoning behind the early review closure.

Add Comment

Click the link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This role-based[35] function is used to view and comment on a selected document section. The sections display on the left side of the screen in a 'tree-structure' formation that not only lists all of the sections and their relationship to each other, but also allows transferring directly to a specific section.

Purpose

The Add Comment screen is used to add a comment for a document section. The comment can be about suggesting text additions, changes, recommendations, and so on.

Key Processes and Concepts

- This screen contains two text-entry areas, choose one or both of the following options per comment: **Add Your Comment** or **Proposed Text Changes**.
- For Docu-MART Authored documents, the system tracks changes by default.
- The **Submit to [group]** button is available only for Non-facilitated Reviewers and Lead Reviewers.
- The Lead Reviewer can change the **Requires Response** or **Recommended** value when making the final comment during comment approval process.

[35] For roles: Reviewer, Lead Reviewer, Site Coordinator, and Protocol Specialist--with the task "Review and Comment" assigned for the protocol.

- The **Track Changes** option is available only for non Docu-MART Authored documents[36]. The checkbox beside the 'Copy text below and click the checkbox to Track Changes' must be checked so that changes are tracked from that point on. The term 'copy' is used here because a non Docu-MART authored document is not automatically populated, the copy the section text must be copied from the original document and pasted it in the Proposed Text Changes area.

Steps

1. Signify the priority of the comment by clicking the radio button for **Requires Response** or for **Recommended**.
2. Enter text in one or both of the following:

- **Add Your Comment**: Use this text box to enter instructions, recommendations, or directives. An entire comment or selected text can be copied and pasted from the existing comment. If more typing space is required than appears on the screen, click the **Expand** button to display a larger text box.
- **Proposed Text Changes**: Use this text box to enter actual recommended wording changes by directly adding, deleting, or changing the existing text (in the manner of a standard word processor).

  For a Docu-MART authored document, the section text from the document displays. For a non Docu-MART authored document, copy the section text from the original document and paste it in the Proposed Text Changes area.

3. Click **Compare with original** to see the comparison of existing text to the proposed text changes.
4. Click **Save as Draft**, or **Submit to [group].**

Additional Screen Features

- Click **File Attachment** to attach a file for the comment. The browser for this function works in the standard file location manner.
- Tabs and Navigation buttons appear on this screen that allow easy navigation within Review and Commenting.

To Copy & Paste: Using the mouse pointer, 'sweep' the text that is to be copied from the existing comment down to the Add Your Comment section, then click **Copy & Paste**. The selected text will be pasted into the Add Your Comment section.

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[36] A document that was not authored using Docu-MART's Authoring Tool functions.

Spellchecking:

Within the word processing section of this screen is an icon consisting of the letters '**abc**' beside a **checkmark**. Clicking on that icon begins the spellchecking function.

Add Comment screen elements

The following elements are featured on the Add Comment screen:

Field	How to Use	Description
Section Name	n/a	Name of the selected section receiving the reply.
Add Your Comment	Direct entry	Reason for comment or actual recommended comment text.
Requires Response/ Recommended	Click radio button	Indicates if a response is mandatory or suggested.
Proposed Text Changes	Direct entry	Actual recommended text of reviewer's comment.
Copy text below and click the checkbox to Track Changes	Click checkbox	Appears on **non Docu-MART authored documents only**, clicking the checkbox initiates tracking changes.
File Attachment	Click **Browse**	Select to attach file to this document version; use standard browser functions

Spellchecking

- When the spellcheck icon is clicked, all questionable terms are highlighted. This does not mean that they are incorrect, only that they are not recognized by the word processor’s dictionary. Most likely some of the highlighted terms are correct.
- The spellchecking function works from the top down. For example, the Replace All function works from the current location

to the bottom of the document being checked, it will not replace terms that occur before the Replace All button is clicked.
- The highlighting disappears after a selection has been made on that term.

Each button featured on this screen has a specific spellchecking function:

<table>
<tr><th>Spellchecking Button</th><th>Related Action</th></tr>
<tr><td>Ignore</td><td>Skip this term and accept as is, other occurrences will not be affected.</td></tr>
<tr><td>Ignore All</td><td>Skip the term and all identical ones from this location forward.</td></tr>
<tr><td colspan="2">The ‘Suggestions’ text box is an important spellchecking tool. See the Using the Suggestions Text Box section near the end of this topic for details.</td></tr>
<tr><td>Replace</td><td>Exchange this highlighted term for the contents in the Replace With text box, other occurrences will not be affected.</td></tr>
<tr><td>Replace All</td><td>Exchange this highlighted term and all identical ones for the contents in the Replace With text box, from this location forward.</td></tr>
</table>

Using the Suggestions text box:

The spellchecker will try to make suggestions about the correct term or proper spelling for each highlighted word. If there is only one suggestion, the same term appears in the Replace With and the Suggestions text boxes. If there is more than one suggestion, scroll though those terms until the correct one appears (and is selected), then click Replace or Replace All, whichever one is appropriate.

Add/Edit Executive Summary

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This CTEP Lead Reviewer function provides information to populate the PRC[37] Comments Report. Attachments can also be added to support the Lead Reviewer's information.

Purpose

The Executive Summary screen is used by the CTEP Lead Reviewer to provide a brief overview or synopsis of the protocol for the PRC. The summary may include protocol information such as background, rationale, objectives, and comparison to other studies.

Key Process and Concepts

- CTEP Lead Reviewer **cannot** add or edit the Executive Summary if:

  The "Review & Comment by CTEP" stage is complete (for a Sequential review).

  The "Review & Comment by All" stage is complete (for a Collaborative review).

- After the Executive Summary has been submitted, the button name becomes **View Executive Summary**.
- When **Completed Initial Review & Comment** is clicked to complete the R & C task, an information message displays indicating that the Executive Summary has not been entered. There are options to complete the Review, Comment & Reply by CTEP, or to add the Executive Summary before continuing.
- When **Completed Initial Review & Comment** is clicked to complete the R & C task and the Executive Summary has a 'Draft' status, an information message displays concerning the status. There are options to complete the Review, Comment & Reply by CTEP, or to edit the Executive Summary before continuing.

[37] Protocol Review Committee

Steps

1. Enter the appropriate text in the Executive Summary for PRC text box.
2. Click the appropriate button:
   - **Save As Draft**: As long as there is a 'Draft' status and the Review and Commenting stage is open, the Executive Summary information can be changed.
   - **Submit to CTEP**: A confirmation message is displayed, since the Executive Summary cannot be changed after it has been submitted to CTEP.

Additional Features

Viewing the Executive Summary:

Once the Executive Summary is submitted and the button name becomes **View Executive Summary**, clicking on that button displays the Executive Summary View screen.

Add Attachment

1. Click inside the **Add Attachment text box**.
2. Enter the complete path of the attachment (location, filename, and extension) or use the **Browse** button to access the file. This function works as a standard browser.

   Optional

   After the attachment has been added:

- Click the **View** button to see the contents of the attachment.
- Click the **Delete File** checkbox in the Remove column to delete the attachment from the document.
- Click the Browse button in the Modify column to change the existing attachment.

Sort Comments By:

The following steps specify how the information from this screen is to be displayed in the PRC Comments report (the created output):

1. Accept the default of (sort) **By Sections**, or click **By Reviewer** to have the output delineated by reviewer name.
2. Accept the default of **All** to show comments from all reviewers, or **select a specific name** from the drop-down list.

Choose Report Format:

A preview of the Executive Summary information can be displayed in a choice of formats.

1. Select the format by clicking on the appropriate radio button, HTML or MS-Word.
2. Click **Save as Draft and View PRC Report** to save the Executive Summary with a 'Draft' status and to view a read-only PRC Report.

Executive Summary screen elements

Document identifiers appear automatically near the top of the screen.

The following elements are featured on the Executive Summary screen:

Field	How to Use	Description
Executive Summary for PRC	Direct entry	Text that summarizes or describes comments to be included in the PRC Comments Report.
Add Attachment	Use Browse button	Supporting documentation for the PRC Comments Report.
PRC Comments Report section:		
Sort Comments (by Section or by Reviewer)	Click radio button	Indicates how the information entered on this screen is to appear in the PRC Comments report.
Include Comments by Reviewer	Use drop-down list	Indicates the reviewers whose comments are to appear in the PRC Comments report.
Choose Report Format	Click radio button	Indicates in what format the preview is to display after the Save & View Comments Report is clicked.

Add Reply

Click the link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This role-based[38] function is used to view and reply to a comment. The sections display on the left side of the screen in a 'tree-structure' formation that not only lists all of the sections and their relationship to each other, but also allows transferring directly to a specific section (and then that section's comments).

Purpose

The Add Reply screen is used to respond to a specific comment.

Key Processes and Concepts

- The original comment, featured near the top with the role of the person who wrote it, cannot be changed. It can be copied into the Add Your Comment section (which is to contain the Reply text) and used as a **basis** for the reply.
- For Docu-MART Authored documents, the system tracks changes by default.
- The Lead Reviewer can change the **Requires Response** or **Recommended** value when making the final comment during comment approval process.
- The **Track Changes** option is available only for non Docu-MART Authored documents[39]. The checkbox beside the 'Copy text below and click the checkbox to Track Changes' must be checked so that changes are tracked from that point on. The term 'copy' is used here because a non Docu-MART authored document is not automatically populated, the copy the section text must be copied from the original document and pasted it in the Proposed Text Changes area.

[38] For roles: Reviewer, Lead Reviewer, Site Coordinator, and Protocol Specialist--with the task "Review and Comment" assigned for the protocol.

[39] A document that was not authored using Docu-MART's Authoring Tool functions.

Steps

1. Signify the priority of the reply by clicking the radio button for **Requires Response** or for **Recommended**.
2. Complete the Add Your Comment performing one of the following actions:
   a. Typing the Reply text directly into the Add Your Comment section. If more typing space is required than appears on the screen, click the **Expand** button to display a larger text box.
   b. Copying the original comment text and pasting it in the Add Your Comment section. Then add to, change, or qualify the original comment text.

      To Copy & Paste: Using the mouse pointer, 'sweep' the text that is to be copied from the existing comment down to the Add Your Comment section, then click **Copy & Paste**. The selected text will be pasted into the Add Your comment section.

3. Click **Compare with original** to see the comparison of existing text to the proposed text changes.
4. Click **Save as Draft, Save Reply, Submit to All,** or **Set to Accept**.

   Save Reply saves the reply text. It can then be viewed but not edited. **Set to Accept** is available only to Lead Reviewers and non-facilitated users.

Additional Screen Features

- Tabs and Navigation buttons appear on this screen that allow easy navigation within Review and Commenting.

Spellchecking:

Within the word processing section of this screen is an icon consisting of the letters '**abc**' beside a **checkmark**. Clicking on that icon begins the spellchecking function.

Add Reply screen elements

The following elements are featured on the Add Reply screen:

Field	How to Use	Description
Section Name	n/a	Name of the selected section receiving the reply.

Reviewers Reply	Direct entry	Reason for reply or qualifying information for the reply.
Requires Response/ Recommended	Click radio button	Indicates if a response is mandatory or suggested.
Proposed Text Changes	Direct entry	Actual recommended text of reviewer's reply.
Copy text below and click the checkbox to Track Changes	Click checkbox	Appears on **non Docu-MART authored documents only**, clicking the checkbox initiates tracking changes.
File Attachment	Click **Browse**	Select to attach file to this document version; use standard browser functions

Build Consensus Review

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This function is by the CTEP Lead Reviewer to manage documents with a CTEP Sequential review track. Comments to be submitted to the group are selected here. Any comment that is not ready to included in the review can be added after modification of the text.

Purpose

The Build Consensus Review screen is used to collect and submit CTEP comments to the appropriate group.

Key Processes and Concepts

- For the **Expand Comment Thread** button to appear, there must be at least one comment and at least one reply.

- Three checkboxes automatically display for each comment, **Add to CTEP CR, Modify & Add to CTEP CR,** and **Mark for Rejection** (the Mark for Rejection checkbox appears with all pending comments).
- If a comment is marked for rejection, a reason must be given.
- For an **Expanded Comment Thread** (a comment with one or more replies), the Resolve Comments – Expanded Comment Thread screen displays after clicking the **Expand Comment Thread** button.
- If a comment has a Show History link associated with it, clicking on the link displays the history of a previous discussion related to this comment.
- If a comment has a 'Draft' status, it has an Edit and a Delete link.
- Click on the View button to display the contents of the file attachment.

Steps

For an non-expanded comment thread (where there is no Expand Comment Thread button):

1. Click on the appropriate checkbox, **Add to CTEP CR, Modify & Add to CTEP CR,** or **Mark for Rejection** (Reminder: Mark for Rejection appears only if the resolved state is open).
   a. If the **Modify and Add to CTEP CR** checkbox is selected, the Modify for Consensus Review screen displays.
   b. If the **Mark for Rejection checkbox** is selected, the Reason for Rejection text box displays. Enter the reason that the comment is being rejected, then click **OK**.
2. Select one of the following options:
   a. Click **Save Changes** to save the checkbox selections
   b. Click **Save & Next** to save the checkbox selections and transfer to the Confirm Consensus Review screen.
   c. Click **Next** to transfer to the Confirm Consensus Review screen without saving.

For an expanded comment thread, click the **Expand Comment Thread** button.

Additional Screen Features

If a comment has a 'Draft' status, an Edit and a Delete link displays. If necessary, click the appropriate link to proceed.

Spellchecking:

Within the word processing section of the Build Consensus Review screen is an icon consisting of the letters '**abc**' beside a **checkmark**. Clicking on that icon begins the spellchecking function.

Attachments:

A comment marked with the **paper clip icon** indicates that the comment has an attachment.

1. Click the **link related to the icon**. The comment details are shown and the file name displays, as well as an associated View button.
2. Click on the **View** button to display the contents of the file attachment.

Build Consensus Review - Expanded Comment Thread

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features

Introduction

This function is by the CTEP Lead Reviewer to manage documents with a CTEP Sequential review track. Comments on Expanded Comment Threads that are to be submitted to the group are selected here. Any comment that is not ready to included in the review can be added after modification of the text.

Purpose

The Build Consensus Review - Expanded Comment Thread screen is used to collect and submit CTEP comments on Expanded Comment Threads to the appropriate group.

Key Processes and Concepts

- On this screen, each comment is automatically expanded.
- Two checkboxes automatically display for each comment, **Add to CTEP CR** and **Modify & Add to CTEP CR**.
- A **Reject Thread** button appears. If a comment is rejected, a reason must be included.

- If a comment has a Show History link associated with it, clicking on the link displays the history of a previous discussion related to this comment.
- If a comment has a 'Draft' status, it has an Edit and a Delete link.

Steps

1. Click on the appropriate checkbox, **Add to CTEP CR, Modify & Add to CTEP CR**, or click on the **Reject Thread** button*.*
   a. If the Modify & Add to CTEP CR checkbox is selected, the Modify for Consensus Review screen displays.
   b. If the **Reject Thread** button is clicked, the Reason for Rejection text box displays. Enter the reason that the comment is being rejected, then click **OK**.
2. Click **Save** to save the changes and return to the Build Consensus Review screen.

Additional Screen Features

If a comment has a 'Draft' status, an Edit and a Delete link displays. If necessary, click the appropriate link to proceed.

Any comments from Reconcile Screen will be denoted by an exclamation mark (**!**) surrounded by yellow.

Build Consensus Review screen elements

The following elements are featured on the Build Consensus Review screen:

Field	How to Use	Description
Subject (Main Comment Thread)	Direct entry	Shown using filter, the subject (or title) of the comment.
Document Section	Drop-down list	Shown using filter, section of document to locate.
By Reviewer Name	Drop-down list	Shown using filter, name of reviewer to be included in filter--used in combination with radio buttons:
All	Click radio button	Show threads where selected reviewer **participated** (used

		with By Reviewer Name).
Initiated	Click radio button	Show only threads **started** by the selected reviewer Show threads where selected reviewer **participated** (used with By Reviewer Name).
All	Click radio button	Show all threads regardless of status.
Pending	n/a	Show all threads that are awaiting a new status (pending).
Comment/Replies	n/a	Comment type and subject.
Total Replies	n/a	Total number of replies for the associated comment.
Reqd/Reco (Required or Recommended)	n/a	Indicates if comment review is required or recommended, as selected on the Add Comment screen.
Changed Text	n/a	Checkmark indicates that there has been a change in section content (based on the published version of that section).
Reviewer (Organization)	n/a	Reviewer who made the comment and his/her organization.
Comment Status (Date)	n/a	Date current comment status was assigned.
Comment Status	n/a	'Yes' if the comment has been confirmed, 'No, if it is

		unconfirmed.
Select the Action	Click checkbox or button	Next step to be taken with this comment, appropriate checkbox or button appears automatically.

CR Signature

Click the link to advance to section or scroll down:

Purpose	Steps

Purpose

Use the CR Signature form to enter the information that appears below the Lead Reviewer's signature. The information you enter then appears on the CTEP Consensus Review Report.

The system automatically pre-populates the CR Signature form with the Lead Reviewer's name and degrees. You can then update the **CC:** and **Enclosures:** areas with the appropriate information for the Lead Reviewer.

Steps

Perform the following steps to enter the Lead Reviewer's signature information:

1. In the **CC:** and **Enclosures:** areas, enter the information to appear below the Lead Reviewer's signature.
2. Choose from the following options:

- Choose **Preview CTEP Consensus Review Report** to see the CTEP Consensus Review Report with the information you have entered.
- Choose **Save** to save the signature information.
- Choose **Save & Previous** to save the ranks given and go to the previous step.
- Choose **Previous** to go to the previous step.
- Choose **Save & Completed CR** to save the signature information and close the CR.

To preview the CTEP Consensus Review report:

Clicking the **Preview CTEP Consensus Review Report** button allows a draft copy of this report to be reviewed.

1. Select the output format by clicking on the radio button associated with HTML or MS Word.
2. Click **Generate Report**.

Comment Statuses

Status concept information is featured after the following table,which shows the Comment Statuses with their definitions and status owners.

Comment Status	Definition	Status Owner
Draft	Drafted comment/ review comment that is saved for later posting.	All Reviewers
Withdrawn	Comment thread is withdrawn from further review.	All Reviewers - Thread Owners All Lead Reviewers
Submit to CTEP/[CTEP_ID]	Comment thread is visible to all reviewers of the specific group of reviewers.	All Reviewers
Accepted by [CTEP_ID]	The comment thread is accepted by site.	Site Lead Reviewers
Accepted by CTEP	The comment thread is accepted for changes to be incorporated.	CTEP Lead Reviewers
Rejected	The change request is no longer available for discussion.	CTEP Lead Reviewers Site Lead Reviewers
Incorporated	The accepted comment thread has been incorporated into the specific section.	Site Coordinators

Not Incorporated	The accepted comment thread has not been incorporated.	Site Coordinators

Status Concepts

- The above statuses are applicable for Review Comment Main Thread only. The replies to the main thread will have only two statuses, 'Draft' and 'Send'.
- Users have the ability to enter optional 'Status Change Comments' for each status change.
- 'Withdrawn' and 'Rejected' statuses close the comment thread.
- 'Accepted by Site' Status closes the commenting thread and also provides an option to enter a 'Final Review Comment' for the thread if the user thinks that the original comment has changed during the course of discussions.

Note: 'Unresolved' comment status will not be available as a choice while signing off individual comments. It will be provided as an option only at the time of completing the stage task 'Sign Off' for the entire document. This 'Unresolved' comment status will also not be available if the study status is 'Approved'.

Incorporate Comments

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This function is used to indicate which comments are ready to be combined and prepared for submission. Any comment that is not ready to be incorporated can be accepted after modification of the text. This modification can be performed and then incorporated, without the need to proceed to another or previous function.

Purpose

The Incorporate Comments screen is used to indicate if a comment is ready to be incorporated into the document, and if not—why, and what needs to be done to make it ready.

Key Processes and Concepts

- For the **Expand Comment Thread** button to appear, there must be at least one comment and at least one reply.
- Two checkboxes automatically display for each comment, **Mark for Incorporation** and **Mark to Not Incorporate**.
- For comments where the resolved state is open, a **Mark for Rejection** checkbox appears. If a comment is rejected, a reason must be included.
- For an **Expanded Comment Thread** (a comment with one or more replies), the Incorporate Comments – Expanded Comment Thread screen displays after clicking the **Expanded Comment Thread** button.
- If a comment has a Show History link associated with it, clicking on the link displays the history of a previous discussion related to this comment.

Steps

For an non-expanded comment thread (where there is no Expand Comment Thread button):

1. Click on the appropriate checkbox, **Mark for Incorporation, Mark to Not Incorporate,** or **Mark for Rejection** (Reminder: Mark for Rejection appears only if the resolved state is open).
   a. If the **Mark to Not Incorporate** checkbox is selected, the Modify for Incorporate Comments screen displays.
   b. If the **Mark for Rejection checkbox** is selected, the Reason for Rejection text box displays. Enter the reason that the comment is being rejected, then click **OK**.
2. Click **Save & Next** to save the checkbox selections and transfer to the Confirm Incorporate Comments screen, or click **Next** to transfer to the Confirm Incorporate Comments screen without saving.

For an expanded comment thread, click the Expand Comment Thread button.

Additional Screen Features

Attachments:

A comment marked with the **paper clip icon** indicates that the comment has an attachment.

1. Click the **link related to the icon**. The comment details are shown and the file name displays, as well as an associated View button.

2. Click on the **View** button to display the contents of the file attachment.

Tabs and Navigation buttons appear on this screen that allow easy navigation within Review and Commenting.

Filtering:

Use the filter to narrow the list of displayed comments by entering identifying information for the appropriate comment or comments.

An initial filter displays on the screen automatically when the screen opens.

1. Click the **All** radio button or **Pending** radio button. It defaults to Pending (awaiting status change).
2. Click **Go**.

Optional: A secondary filter function is available by clicking Show Filter.

1. Complete the appropriate fields by direct entry:
- Subject – Main Comment Thread
- Document Section.
2. Click the **All** or **Initiated** radio button.

   Selecting **All** returns all comments where the person selected in the next step participates in any way. Selecting **Initiated** returns all comments where the person selected in the next step started the comment.

3. Select the appropriate reviewer name from the By Reviewer Name drop-down list.
4. Click **All** radio button and **Pending** radio button.
5. Click **Go**.

Incorporate Comments - Expanded Comment Thread

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features

Introduction

This function is used to indicate which comments on an Expanded Comment Thread are ready to be combined and prepared for submission. Any comment that is not ready to be incorporated can be accepted after modification of the text. This modification can be performed and then incorporated, without the need to proceed to another or previous function.

Purpose

The Incorporate Comments - Expanded Comment Thread screen is used to indicate if a comment on an Expanded Comment Thread is ready to be incorporated into the document.

Key Processes and Concepts

- On this screen each comment is automatically expanded.
- Two checkboxes automatically display for each comment, **Mark for Incorporation** and **Modify & Mark for Incorporation**.

- A **Mark to Not Incorporate** button appears near the top of the screen. If a comment is marked for 'not incorporation', a reason must be included.

Steps

1. Click on the appropriate checkbox, **Mark for Incorporation** or **Modify & Mark for Incorporation**, or click on the **Mark to Not Incorporate** button.
    a. If the **Modify & Mark for Incorporation** checkbox is selected, the Modify for Incorporate Comments screen displays.
    b. If the **Mark to Not Incorporate** button is clicked, the Reason for Rejection text box displays. Enter the reason that the comment is being not incorporated, then click **OK**.
2. Click **Save** to save the changes and return to the Incorporate Comments screen.

Additional Screen Features

- A comment with a 'Draft' status will have a 'Mark for Incorporation" option.
- If a comment has a 'Draft' status, an Edit and a Delete link displays. If necessary, click the appropriate link to proceed.

Incorporate Comments screen elements

The following elements are featured on the Incorporate Comments screen:

Field	How to Use	Description
Subject (Main Comment Thread)	Direct entry	Shown using filter, the subject (or title) of the comment.
Document Section	Drop-down list	Shown using filter, section of document to locate.
By Reviewer Name	Drop-down list	Shown using filter, name of reviewer to be included in filter--used in combination with radio buttons:
All	Click radio button	Show threads where selected reviewer **participated** (used with By Reviewer Name).
Initiated	Click radio button	Show only threads **started** by the selected reviewer Show threads where selected reviewer **participated** (used with By Reviewer Name).
All	Click radio button	Show all threads regardless of status.
Pending	n/a	Show all threads that are awaiting a new status (pending).
Comment/Replies	n/a	Comment type and subject.
Total Replies	n/a	Total number of replies for the associated comment.
Reqd/Reco	n/a	Indicates if comment review

(Required or Recommended)		is required or recommended, as selected on the Add Comment screen.
Changed Text	n/a	Checkmark indicates that there has been a change in section content (based on the published version of that section).
Reviewer (Organization)	n/a	Reviewer who made the comment and his/her organization.
Comment Status (Date)	n/a	Date current comment status was assigned.
Comment Status	n/a	'Yes' if the comment has been confirmed, 'No, if it is unconfirmed.
Select the Action	Click checkbox or button	Next step to be taken with this comment, appropriate checkbox or button appears automatically.

Modify for Consensus Review

Click link to advance to section or scroll down:

Introduction	Purpose	Steps	Additional Features

Introduction

This function is used to modify a comment on an Expanded Comment Thread so that it can be accepted. These instructions are for the Modify for Consensus Review screen and the Modify for Consensus Review - Expanded Comment Thread screen.

Purpose

The Modify for Consensus Review screen is used to make (usually minor) changes in a comment in preparation for acceptance.

Steps

1. Signify the priority of the comment by clicking the radio button for **Requires Response** (the default) or for **Recommended**.
2. Enter text in one or both of the following:

- **Add Your Comment**: Use this text box to enter instructions, recommendations, or directives. An entire comment or selected text can be copied and pasted from the existing comment. If more typing space is required than appears on the screen, click the **Expand** button to display a larger text box.
- **Proposed Text Changes**: Use this text box to enter actual recommended wording changes by directly adding, deleting, or changing the existing text (in the manner of a standard word processor).

  For a Docu-MART authored document, the section text from the document displays. For a non Docu-MART authored document, copy the section text from the original document and paste it in the Proposed Text Changes area. Prior to making the changes, check the Track Changes checkbox. The changes will then be visible when the **Show Difference** button is clicked.

To Copy & Paste: Using the mouse pointer, 'sweep' the text that is to be copied from the existing comment down to the Add Your Comment section, then click Copy & Paste. The selected text will be pasted into the Add Your Comment section.

3. Click **Show Difference** to see the comparison of existing text to the proposed text changes.
4. Click **Save as Draft** or **Add to CTEP CR** to return to the Build Consensus Review screen.

Additional Features

Click **File Attachment** to attach a file for the comment. The browser for this function works in the standard file location manner.

Spellchecking:

Within the word processing section of this screen is an icon consisting of the letters '**abc**' beside a **checkmark**. Clicking on that icon begins the spellchecking function.

Optional for the Modify for Consensus Review - Expanded Comment Thread screen:

1. **Click the Show Entire Comment Thread button to see all of the comment thread.**

Modify for Incorporate Comments

Click link to advance to section or scroll down:

Introduction	Purpose	Steps	Additional Features

Introduction

This function is used to modify a comment so that it is suitable for incorporation. Although it appears similar to other 'comments' screens it is specific to comment modification prior to being incorporated.

Purpose

The Modify for Incorporate Comments screen is used to make (usually minor) changes in a comment and mark it for incorporation.

Steps

1. Signify the priority of the comment by clicking the radio button for **Requires Response** (the default) or for **Recommended**.
2. Enter text in one or both of the following:

- **Add Your Comment**: Use this text box to enter instructions, recommendations, or directives. An entire comment or selected text can be copied and pasted from the existing comment. If more typing space is required than appears on the screen, click the **Expand** button to display a larger text box.
- **Proposed Text Changes**: Use this text box to enter actual recommended wording changes by directly adding, deleting, or changing the existing text (in the manner of a standard word processor).

  For a Docu-MART authored document, the section text from the document displays. For a non Docu-MART authored document, copy the section text from the original document and paste it in the Proposed Text Changes area. Prior to making the changes, check the Track Changes checkbox. The changes will then be visible when the **Show Difference** button is clicked.

To Copy & Paste: Using the mouse pointer, 'sweep' the text that is to be copied from the existing comment down to the Add Your Comment section, then click Copy & Paste. The selected text will be pasted into the Add Your Comment section.

3. Click **Compare with original** to see the comparison of existing text to the proposed text changes.
4. Click **Save as Draft** or **Mark for Incorporation** to return to the Incorporate Comments screen. Selecting **Save as Draft** allows future changes, after which the comment can be marked for incorporation.

Additional Features

Click **File Attachment** to attach a file for the comment. The browser for this function works in the standard file location manner.

Spellchecking:

Within the word processing section of this screen is an icon consisting of the letters '**abc**' beside a **checkmark**. Clicking on that icon begins the spellchecking function.

Modify for Resolve Comments

Click link to advance to section or scroll down:

Introduction	Purpose	Steps	Additional Features

Introduction

This function is used to modify a comment on an Expanded Comment Thread so that it can be resolved. These instructions are for the Modify for Resolve screen and the Modify for Resolve - Expanded Comment Thread screen.

Purpose

The Modify for Resolve Comments screen is used to make (usually minor) changes in a comment in preparation for incorporation.

Steps

1. Signify the priority of the comment by clicking the radio button for **Requires Response** (the default) or for **Recommended**.
2. Enter text in one or both of the following:

- **Add Your Comment**: Use this text box to enter instructions, recommendations, or directives. If more typing space is required than appears on the screen, click the **Expand** button to display a larger text box.
- **Proposed Text Changes**: Use this text box to enter actual recommended wording changes by directly adding, deleting, or changing the existing text (in the manner of a standard word processor).

  For a Docu-MART authored document, the section text from the document displays. For a non Docu-MART authored document, copy the section text from the original document and paste it in the Proposed Text Changes area. Prior to making the changes, check the Track Changes checkbox. The changes will then be visible when the **Show Difference** button is clicked.

To Copy & Paste: Using the mouse pointer, 'sweep' the text that is to be copied from the existing comment down to the Add Your Comment section, then click Copy & Paste. The selected text will be pasted into the Add Your Comment section.

3. Click **Compare with original** to see the comparison of existing text to the proposed text changes.
4. Click **Save as Draft** or **Mark for Acceptance** to return to the Resolve Comments screen.

Additional Features

Click **File Attachment** to attach a file for the comment. The browser for this function works in the standard file location manner.

Spellchecking:

Within the word processing section of the Add Reply screen is an icon consisting of the letters '**abc**' beside a **checkmark**. Clicking on that icon begins the spellchecking function.

Optional for the Modify for Resolve - Expanded Comment Thread screen:

1. **Click the Show Entire Comment Thread button to see all of the comment thread.**

Review Comment Navigator

Introduction:

Clicking on the **Where Am I?/Next Steps** button displays the Review Comment Navigator, a location and progress bar that is accessible throughout the Review, Comment & Reply process. It is a duplicate, 'portable' version of the Suggested Steps on the Review and Commenting Main screen. Remaining visible while using Review, Comment & Reply, it can be used for reference purposes as well as efficient navigation.

Using the Review Comment Navigator:

A. The steps change as the Task is switched in the drop-down list.
B. The steps display in three different formats:
   - **Blue text** denotes the Current Step. It works as a 'You are here' function.
   - **Brown text featured with a link** indicates that the step has not been completed; clicking on the link displays that step's entry screen.
   - **Black text** without a link indicates that the step has been completed.
C. Clicking on the **Review & Commenting Main link** near the top center displays the Review and Commenting Main screen at any point. This is particularly helpful when there is a feeling of being 'lost' within the various Review and Commenting screens.
D. Click the **Close** button or the X box in the upper right corner to close the navigator.

Note: Each Review Comment Navigator has a Task Completion step as its final step (this Task Completion step is also featured in the Suggested Steps section of the Review and Commenting Main screen). If the task cannot be completed because there are some pending actions that prevent it, clicking on the this Task Completion step in the Review Comment Navigator transfers the user to the R & C Main screen, where the Task Completion Alert message displays.

Rank Comments

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

The Rank Comments screen displays the comments that reviewers initiate, grouped by 'Required' or 'Recommended' for ease of ranking.

The screen is accessible from the Review and Commenting – Main screen. After ranking their comments, reviewers can return to the main screen by clicking the **Back to R&C Main Screen** button.

Purpose

Lead Reviewers can use the Rank Comments screen to give a rank number for the comments entered. This option is available for the 'Review, Comment & Reply by CTEP' and 'Reconcile, Review, Comment & Reply' tasks.

Key Processes and Concepts

- Within the groups 'Required' and 'Recommended', the comments are sorted by section.
- Reviewers can change the ranks within a group and save them. This sorts the comments within the group by rank assigned, followed by comments that are not assigned rank. The comments that are not assigned rank are ordered by section.
- Entering a duplicate rank causes the system to re-arrange the numbers. The rank cannot exceed the number of comments within that group.

Steps

If necessary, show all comments by clicking on the plus (+) sign to the left of the Comments heading.

1. Enter the assigned ranks.
2. Click **Save & Completed Initial Review**.

   The system saves the ranks given and tries to complete the R&C by CTEP task.

At the time of R&C stage complete, you are prompted to assign the rank of any remaining comments.

- Choose **Yes** to go to the Rank Comments screen to assign the ranks to your remaining comments.
- Choose **No** to complete the R&C task.
- Choose **Cancel** to continue on the same screen.

Additional Screen Features

The **Sort by Comment Rank** button lets you sort the comments within a group by their assigned rank.

Rank Comments screen elements

The following elements are featured on the Rank Comments screen:

Field	How to Use	Description
NCI Document #	n/a	Unique identifier for a document. If the document is submitted by a group, the group document number is used. If not, the identifier is system-generated.
Document Type	n/a	Category, or type, that describes this document.
Local Document #	n/a	Identifying code for this document, as determined by its initiating group
Version Date	n/a	Date current version was created.
Submission Type Track Type	n/a	Category or type of this submission, such as Pre-Submission or CTEP Submission. Type of review track, such as Sequential or Collaborative.
Roles	n/a	Function of the reviewers for this protocol: Lead Reviewer, Reviewer, or Site Coordinator. The Site Coordinator selection is used by the actual Site Coordinator to delegate a 'substitute'.
Title	n/a	Complete name of this document.
Save & Completed	Click	Instructs the system to save the ranks given and to complete the

Initial Review	button	R&C by CTEP task.
Comments (Section Name)	n/a	Title and section of the comment.
Changed Text	n/a	Indicates whether the text was changed.
Reviewer (Organization)	n/a	The name and organization of the assigned reviewer.
Status Changed To (Date)	n/a	The date the status was last changed.
Comment Rank	Direct entry	Assign a rank for the comment.
Sort by Comment Rank	Click button	Sorts the comments within a group by their assigned rank.
Clear Ranks	Click button	Clears the ranks assigned within a group.

Rank Consensus Review Comments

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

The Rank Consensus Review Comments screen displays the comments that reviewers initiate, grouped by 'Required' or 'Recommended' for ease of ranking. The screen is accessible from the Review and Commenting – Main screen. After ranking their comments, reviewers can return to the main screen by clicking the **Back to R&C Main Screen** button.

Purpose

Lead Reviewers can use the Rank Consensus Review Comments screen to give a rank number for the comments entered. This option is available for the 'Submit Consensus Review' task.

Key Processes and Concepts

- Within the groups 'Required' and 'Recommended', the comments are sorted by section.
- Reviewers can change the ranks within a group and save them. This sorts the comments within the group by rank assigned, followed by comments that are not assigned rank. The comments that are not assigned rank are ordered by section
- Entering a duplicate rank causes the system to re-arrange the numbers. The rank cannot exceed the number of comments within that group.

Steps

If necessary, show all comments by clicking on the plus (+) sign to the left of the Comments heading.

1. Enter the assigned ranks.
2. Choose from the following options:

- Choose **Save** to save the ranks.
- Choose **Save & Previous** to save the ranks given and go to the previous step (Confirm Consensus Review).
- Choose **Previous** to go to the previous step (Confirm Consensus Review).
- Choose **Save & Next** to save the ranks given and go to the next step (CR Signature).
- Choose **Next** to go to the next step (CR Signature).

Additional Screen Features

The **Sort by Comment Rank** button lets you sort the comments within a group by their assigned rank.

Rank Consensus Review Comments screen elements

The following elements are featured on the Rank Consensus Review Comments screen:

Field	How to Use	Description
NCI Document #	n/a	Unique identifier for a document. If the document is submitted by a group, the group document number is used. If not, the

		identifier is system-generated.
Document Type	n/a	Category, or type, that describes this document.
Local Document #	n/a	Identifying code for this document, as determined by its initiating group
Version Date	n/a	Date current version was created.
Submission Type Track Type	n/a	Category or type of this submission, such as Pre-Submission or CTEP Submission. Type of review track, such as Sequential or Collaborative.
Roles	n/a	Function of the reviewers for this protocol: Lead Reviewer, Reviewer, or Site Coordinator. The Site Coordinator selection is used by the actual Site Coordinator to delegate a 'substitute'.
Title	n/a	Complete name of this document.
Comments (Section Name)	n/a	Title and section of the comment.
Changed Text	n/a	Indicates whether the text was changed.
Reviewer (Organization)	n/a	The name and organization of the assigned reviewer.
Status Changed To (Date)	n/a	The date the status was last changed.

Comment Rank	Direct entry	Assign a rank for the comment.
Sort by Comment Rank	Click button	Sorts the comments within a group by their assigned rank.
Clear Ranks	Click button	Clears the ranks assigned within a group.

Resolve Comments

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This function is used to indicate which comments are ready to be resolved and prepared for incorporation. Any comment that is not ready to be resolved can be accepted after modification of the text. Site Coordinators and Lead Reviewers use this screen, with very slightly different functionality.

Purpose

The Resolve Comments screen is used to manage the resolution of submitted comments.

Key Processes and Concepts

- In preparation for resolving comments, look for the unresolved comments that are either **Submitted by CTEP** or **Submitted to [group]**.
- By resolving, a Site Coordinator automatically adds the comment to the incorporate list. It is then ready to confirm.
- A Lead Reviewer can reject a comment on the Confirm to Resolve screen, even if the Site Coordinator accepts it.

- For the **Expand Comment Thread** button to appear, there must be at least one comment and at least one reply.
- Two checkboxes automatically display for each comment, **Mark for Acceptance** and **Modify and Mark for Acceptance.**

- For comments where the resolution is 'open', a **Mark for Rejection** checkbox appears. If a comment is rejected, a reason must be included.
- For an **Expanded Comment Thread** (a comment with one or more replies), the Resolve Comments – Expanded Comment Thread screen displays after clicking the **Expand Comment Thread** button.
- If a comment has a Show History link associated with it, clicking on the link displays the history of a previous discussion related to this comment.
- If a comment has a 'Draft' status, it has an Edit and a Delete link.

Steps

For an non-expanded comment thread (where there is no Expand Comment Thread button):

1. Click on the appropriate checkbox, **Mark for Acceptance, Modify and Mark for Acceptance,** or **Mark for Rejection** (Reminder: Mark for Rejection appears only if the resolved state is open).
    a. If the **Modify and Mark for Acceptance** checkbox is selected, the Modify for Resolve Comments screen displays.
    b. If the **Mark for Rejection checkbox** is selected, the Reason for Rejection text box displays. Enter the reason that the comment is being rejected, then click **OK**.
2. Select one of the following options:

- Click **Save Changes** to save the checkbox selections.
- Click **Save & Next** to save the checkbox selections and transfer to the Confirm Resolve Comments screen.
- Click **Next** to transfer to the Confirm Resolve Comments screen without saving.

For an expanded comment thread, click the **Expand Comment Thread** button.

Additional Screen Features

Attachments:

A comment marked with the **paper clip icon** indicates that the comment has an attachment.

1. Click the **link related to the icon**. The comment details are shown and the file name displays, as well as an associated View button.

2. Click on the **View** button to display the contents of the file attachment.

If a comment has a 'Draft' status, an Edit and a Delete link displays. If necessary, click the appropriate link to proceed.

Tabs and Navigation buttons appear on this screen that allow easy navigation within Review and Commenting.

Filtering:

Use the filter to narrow the list of displayed comments by entering identifying information for the appropriate comment or comments.

An initial filter displays on the screen automatically when the screen opens.

1. Click the **All** radio button or **Pending** radio button. It defaults to Pending (awaiting status change).
2. Click **Go**.

Optional: A secondary filter function is available by clicking Show Filter.

1. Complete the appropriate fields by direct entry:
- Subject – Main Comment Thread
- Document Section.
2. Click the **All** or **Initiated** radio button.

   Selecting **All** returns all comments where the person selected in the next step participates in any way. Selecting **Initiated** returns all comments where the person selected in the next step started the comment.

3. Select the appropriate reviewer name from the By Reviewer Name drop-down list.
4. Click **All** radio button and **Pending** radio button.
5. Click **Go**.

Resolve Comments - Expanded Comment Thread

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features

Introduction

This function is used to indicate which comments on an Expanded Comment Thread are ready to be resolved and prepared for incorporation. Any comment that is not ready to be resolved can be accepted after modification of the text. Site Coordinators and Lead Reviewers use this screen, with very slightly different functionality.

Purpose

The Resolve Comments - Expanded Comment Thread screen is used to indicate if a comment on an Expanded Comment Thread should or can be resolved and incorporated into the document.

Key Processes and Concepts

- On this screen, each comment is automatically expanded.
- In preparation for resolving comments, look for the unresolved comments that are either **Submitted by CTEP** or **Submitted to [group]**.
- By resolving, a Site Coordinator automatically adds the comment to the accept list. It is then ready to confirm.
- A Lead Reviewer can reject a comment on the Confirm to Resolve screen, even if the Site Coordinator accepts it.

- Two checkboxes automatically display for each comment, **Mark for Acceptance** and **Modify and Mark for Acceptance**.
- A **Reject Thread** button appears. If a comment is rejected, a reason must be included.
- If a comment has a Show History link associated with it, clicking on the link displays the history of a previous discussion related to this comment.
- If a comment has a 'Draft' status, it has an Edit and a Delete link.

Steps

1. Click on the appropriate checkbox, **Mark for Acceptance, Modify and Mark for Acceptance,** or click on the **Reject Thread** button.
   a. If the Modify and Mark for Acceptance checkbox is selected, the Modify for Resolve Comments screen displays.
   b. If the **Reject Thread** button is clicked, the Reason for Rejection text box displays. Enter the reason that the comment is being rejected, then click **OK**.
2. Click **Save** to save the changes and return to the Resolve Comments screen.

Additional Screen Features

If a comment has a 'Draft' status, an Edit and a Delete link displays. If necessary, click the appropriate link to proceed.

Resolve Comments screen elements

The following elements are featured on the Resolve Comments screen:

Field	How to Use	Description
Subject (Main Comment Thread)	Direct entry	Shown using filter, the subject (or title) of the comment.
Document Section	Drop-down list	Shown using filter, section of document to locate.
By Reviewer Name	Drop-down list	Shown using filter, name of reviewer to be included in filter--used in combination with radio buttons:
All	Click radio button	Show threads where selected reviewer **participated** (used with By Reviewer Name).
Initiated	Click radio button	Show only threads **started** by the selected reviewer Show threads where selected reviewer **participated** (used with By Reviewer Name).
All	Click radio button	Show all threads regardless of status.
Pending	n/a	Show all threads that are awaiting a new status (pending).
Comment/Replies	n/a	Comment type and subject.
Total Replies	n/a	Total number of replies for

		the associated comment.
Reqd/Reco (Required or Recommended)	n/a	Indicates if comment review is required or recommended, as selected on the Add Comment screen.
Changed Text	n/a	Checkmark indicates that there has been a change in section content (based on the published version of that section).
Reviewer (Organization)	n/a	Reviewer who made the comment and his/her organization.
Comment Status (Date)	n/a	Date current comment status was assigned.
Comment Status	n/a	'Yes' if the comment has been confirmed, 'No, if it is unconfirmed.
Select the Action	Click checkbox or button	Next step to be taken with this comment, appropriate checkbox or button appears automatically.

Show History

Click the link to show the following information:

For the group that owns the thread:

- Once the comment thread status has progressed past 'Posted For Internal Review' and the final comment with a status of 'Submitted', 'Accepted By Site', or 'Accepted By Participant is not the first comment of the thread, the Show History link appears.
- The entire thread then displays after clicking **Show History**.

For a group that does not own the thread:

- When the group that created the comment thread submits the comment thread status, the Show History link does not appear automatically. Once the thread status is changed from 'Submit' and the comment (Final Comment) that changed that status is other than that submitted comment, the Show History link appears. Clicking on the link displays comment history only from the submitted comment, forward.
- When the comment thread status is submitted by the group that created the comment thread and the Submit for External Review button is clicked, the Show History link displays. Clicking on that link shows the entire thread.

Switch User To

- In the Review and Commenting function, a Site Coordinator or Protocol Specialist can perform work for other Docu-MART users.
- If the Site Coordinator or Protocol Specialist is logged on and there are any **delegated users** for the submission, drop-down selection box appears.

  This delegated user is identified on the Assign Reviewers screen when the 'Reviewer Comments entered by Site Coordinator' checkbox is checked (for the Site) or the 'Reviewer Comments entered by Protocol Specialist' checkbox is checked (for CTEP).

- It defaults to the current user, with the delegated users as selection options.
- After selecting the appropriate 'other' user from the Switch User To drop-down list featured on the Review and Commenting Main screen, the switch is made to the delegated user. Changes appear in the User ID information and the Roles column heading, which now states 'Switched User Roles'.
- The Site Coordinator or Protocol Specialist can then perform the tasks assigned to the delegated user.

Note: To return to the Review and Commenting screen for the Site Coordinator or Protocol Specialist, select that role from the drop-down list.

Tabs and Navigation Buttons

To provide efficient maneuvering from one Review and Commenting function to another, **selection tabs** and **navigation buttons** appear on most Review & Commenting screens.

Selection Tabs (click to access):

- **Tasks** displays the Tasks screen, which displays all current tasks.
- **Inbox** displays the Inbox containing notification emails.
- **Reviewers** displays the View/Edit Reviewers screen.
- **Timelines** displays the View/Edit Timeline screen.
- **Help** displays screen-level online help.
- **Logout** closes the screen and ends the Docu-MART session.
- **Review and Commenting** displays the main Review and Commenting screen.

Navigation Buttons (click to access):

- **Where am I?/Next Steps** displays the Review Comment Navigator.
- **Show Document Info** displays additional identifying information for the document.
- **View My Comments** displays the View My Comments screen, which lists all comments for an individual, divided by document sections and for the entire document.
- **View All Comments** displays the View All Comments screen, which lists all (total) comments for a document, broken down by section.

User Role Table

There are specific user roles that determine which screens and functions can be accessed in Docu-MART. The following table lists and describes each user role and its respective functions.

User Role	Functions/Tasks	Docu-MART Access
	Site	
Site Coordinator	Author documents Publish documents for review Assign & notify site reviewers Manage site review timelines Review and comment	Authoring Tool (Full Access) Publish Screen (Full Access) Tasks/Inbox Review & Commenting

	Incorporate changes/comments	
Author	Author documents	Authoring Tool (Limited Access)
Site Lead Reviewer	Access document for review Review and comment Accept/reject comments	Tasks/Inbox Review & Commenting
Site Reviewer	Access document for review Review and comment	Tasks/Inbox Review & Commenting
CTEP		
Protocol Specialist	Assign & notify CTEP reviewers Manage CTEP review timelines Review and Comment	Tasks/Inbox Review & Commenting
CTEP Lead Reviewer	Access document for review Review and comment Accept/reject Comments	Tasks/Inbox Review & Commenting
CTEP Reviewer	Access document for review Review and comment	Tasks/Inbox Review & Commenting

View All Comments

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This is the major function for managing and reviewing all comments and their associated replies for the document, broken down by section. These sections are separated on the screen. Knowing this and other visual aspects of the screen appearance is important to understanding its functions.

Purpose

The View All Comments screen is used to view all comments and replies for a document for the purpose of review or further processing, as indicated in the following information.

Key Processes and Concepts

- When applicable, a comment can be added to the selected section directly from this screen by clicking the **Add Comment** button.
- Each thread also has a Change Status Thread checkbox. Which Change Thread Status box appears depends on the current status.
- For the **Expand Comment Thread** button to appear, there must be at least one comment and, at least one reply.
- The **Reply** button displays only when it is appropriate. For example, if the due date is passed the **Reply** button will not display.
- If a comment has a Show History link associated with it, clicking on the link displays the history of a previous discussion related to this comment.
- Which functions (additional resources) display when a comment link is clicked depend on the thread[40] status.

Steps

If necessary, show all replies and comments for the selected comment by clicking on the plus (+) sign to the left of the link.

1. Click on the appropriate link.

2. Perform the required actions for the comment. The available button options that display for that comment depend on the thread status of the comment. For details, see Key Processes and Concepts.

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[40] A Thread is a comment and all of its replies. The Thread Owner is the person who made that comment.

Note: For any checkbox that displays in the Change Status Thread column, click the checkbox, then click **Save Changes**.

Additional Screen Features

Attachments:

A comment marked with the **paper clip icon** indicates that the comment has an attachment.

1. Click the **link related to the icon**. The comment details are shown and the file name displays, as well as an associated View button.
2. Click on the **View** button to display the contents of the file attachment.

Tabs and Navigation buttons appear on this screen that allow easy navigation within Review and Commenting.

Optional: Click **File Attachment** to attach a file for the comment. The browser for this function works in the standard file location manner. If there is an existing attachment, click the **Edit** link to access the comment and remove and/or change the attachment.

Filtering:

Use the filter to narrow the list of displayed comments by entering identifying information for the appropriate comment or comments.

1. Click **Show Filter**.
2. Select the filtering (search) criteria. Three options display for selecting search criteria:
   - **Subject (Main Comment thread)**, complete by direct entry, text is case-sensitive.
   - **Comment Thread Status**, select from drop-down list.
   - **Document Section**, select from drop-down list.

   More than one of these options can be used, and only comments meeting both or all criteria display.

3. If appropriate, use the drop-drop list to select the role to be used in the filter (such as Site Coordinator, Protocol Specialist, Lead Reviewer, and so on).
4. Click the appropriate radio button:
- **Started By** - displays all threads started by the user.
- **Participated** - displays all threads where the user participated.
5. Click **Go**.
6. Click **Hide Filter** to remove the filtering fields from view (optional).

View All Comments - Expanded Comment Thread

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps

Introduction

This function is an ideal way to focus on reviewing one full comment thread[41], as well as selecting the next actions for each comment or reply in the thread at one time. It maintains a hierarchical structure that makes it easy to see the flow of comments and replies as they occurred.

Purpose

The View All Comments - Expanded Comment Thread screen is used to manage all comments and replies for a single comment thread.

Key Processes and Concepts

- This screen displays expanded – it shows the full comment text and the full text for each reply.
- It is a good screen to use as a view-only screen, since it contains all comment thread text. However, it is chiefly used for selecting subsequent actions for the comment or a reply.
- The Reply to Comment button can also be interpreted as 'reply to a reply'.
- Which checkboxes display in the 'Select only one action below' column depends on factors such as the current status. The following three Docu-MART Review & Commenting Status State Transition Diagrams illustrate the actions that occur for each of the review tracks:
- Status Transition Diagram - Pre-submission only
- Status Transition Diagram - Sequential
- Status Transition Diagram - Collaborative

Steps

1. Click on **only one** of the 'Select only one action below' checkboxes or links per comment or reply.

   For details, see the Checkbox/Action section of Key Processes and Concepts.

[41] A Comment Thread is one comment with one or more replies.

2. Click **Save Changes**.

View All Comments screen elements

The following elements are featured on the View All Comments screen:

Field	How to Use	Description
Subject (Main Comment Thread)	Direct entry	Shown using filter, the subject (or title) of the comment.
Comment Thread Status	Drop-down list	Shown using filter, current assigned status for the comment
Started By/Participated	Drop-down list	Shown using filter, user role--used in combination with radio buttons:
Started	Click radio button	Show only threads **started** by the selected role
Participated	Click radio button	Show threads where selected role **participated**.
Document Section	Drop-down list	Shown using filter, section of document to locate.
Comments/Replies	n/a	Comment subject listing, by section.
Total Replies	n/a	Total number of replies for the associated comment.
Reqd/Reco (Required or Recommended)	n/a	Indicates if comment review is required or recommended, as selected on the Add Comment screen.
Changed Text	n/a	Checkmark indicates that

		there has been a change in section content (based on the published version of that section).
Reviewer (Organization)	n/a	Reviewer who made the comment and his/her organization.
Comment Status (Date)	n/a	Date current comment status was assigned.
Change Thread Status	Click checkbox or button	New status to be assigned to the comment.

View Document-Add/Reply Comment

Click the link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features

Introduction

- This function is used to select and manage the document sections for further processing, as featured in the following text. **It is the starting point for key Review and Commenting screens, such as**:
- View Section Comments
- Add Comment
- Add Reply

Purpose

The View Document-Add/Reply Comment screen is used to view comments and replies for a specific user's comment threads and determine if further actions are required. The actual document appears on the right side of the screen. This screen also provides a mechanism for printing the document.

Key Processes and Concepts

For Docu-MART authored documents, the sections are automatically assigned according to the current template.

Steps

1. In the Document Sections block, expand the tree structure for the section by clicking on the associated plus (+) sign, repeat if necessary. If a number is featured to the right of the selected section link, there are associated comments.
2. Click on the link (still in the Document Sections block) to select the appropriate section or click on the actual text in the document.
   - If it is a Docu-MART authored document, the specific section text appears in the right portion of the screen
   - If it is non Docu-MART authored, it might be necessary to scroll to the text.
3. Click on the **View/Add Comment** button.

   The Add Comment screen to be associated with the selected section displays.

   Note: If the View/Add Comment button does not appear when the View Document-Add/Reply Comment screen first displays, use the mouse pointer navigation function to "move' the window line (featured immediately above the Document Sections title) ***slightly lower*** until the View/Add Comment button appears.

Additional Features

Tabs and Navigation buttons appear on this screen that allow easy navigation within Review and Commenting.

View My Comments

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This is the major function for managing an individual's comment threads and their associated replies, based on the selected section. These sections are separated on the screen. Knowing this and other visual aspects of the screen appearance is important to understanding its functions.

Purpose

The View My Comments screen is used to view comments and replies for a specific user's comment threads and determine if further actions are required.

Key Processes and Concepts

- When applicable, a comment can be added to the selected section directly from this screen by clicking the **Add Comment** button.
- Each thread also has a Change Status Thread checkbox. Which Change Thread Status box appears depends on the current status.
- For the **Expand Comment Thread** button to appear, there must be at least one comment and, at least one reply.
- The **Reply** button displays only when it is appropriate. For example, if the due date is passed the **Reply** button will not display.
- If a comment has a Show History link associated with it, clicking on the link displays the history of a previous discussion related to this comment.
- Once the end date has passed, the comment/reply process is complete, with no further action allowed except by the Lead Reviewer. With an 'end status' such as 'Withdrawn', 'Incorporated', or 'Accepted', no further action is allowed by anyone.
- Which functions (additional resources) display when a comment link is clicked depend on the thread[42] status.

Steps

If necessary, show all replies and comments for the selected comment by clicking on the plus (+) sign to the left of the link.

1. Click on the link (with the descriptive text) for the appropriate comment or reply
2. Perform the required actions for the comment. The available button options that display for that comment depend on the thread status of the comment. For details, see Key Processes and Concepts.

[42] A Thread is a comment and all of its replies. The Thread Owner is the person who made that comment.

Note: For any checkbox that displays in the Change Status Thread column, click the checkbox, then click **Save Changes**.

Additional Screen Features

Attachments:

A comment marked with the **paper clip icon** indicates that the comment has an attachment.

1. Click the **link related to the icon**. The comment details are shown and the file name displays, as well as an associated View button.
2. Click on the **View** button to display the contents of the file attachment.

Tabs and Navigation buttons appear on this screen that allow easy navigation within Review and Commenting.

Optional: With some roles and statuses, a file attachment can be added to a comment.

1. Click **File Attachment** to attach a file for the comment. The browser for this function works in the standard file location manner. If there is an existing attachment, click the **Edit** link to access the comment and remove and/or change the attachment.

Filtering:

Use the filter to narrow the list of displayed comments by entering identifying information for the appropriate comment or comments.

1. Click **Show Filter**.
2. Select the filtering (search) criteria. Three options display for selecting search criteria:
   - **Subject (Main Comment thread)**, complete by direct entry, text is case-sensitive.
   - **Comment Thread Status**, select from drop-down list.
   - **Document Section**, select from drop-down list.

More than one of these options can be used, and only comments meeting both or all criteria display.

3. Click the appropriate radio button:
- **My Threads** - displays all threads started by the user.
- **All Participating Threads** - displays all threads where the user participated.
4. Click **Go**.

5. Click **Hide Filter** to remove the filtering fields from view (optional).

View My Comments - Expanded Comment Thread

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps

Introduction

This function is an ideal way to focus on reviewing a comment thread[43] for the logged-in user, as well as selecting the next actions for each comment or reply in the thread at one time. It maintains a hierarchical structure that makes it easy to see the flow of comments and replies as they occurred.

Purpose

The View My Comments - Expanded Comment Thread screen is used to manage all comments and replies for a comment thread for a single user.

Key Processes and Concepts

- This screen displays expanded – it shows the full comment text and the full text for each reply.
- It is a good screen to use as a view-only screen, since it contains all comment thread text. However, it is chiefly used for selecting subsequent actions for the comment or a reply.
- The Reply to Comment button can also be interpreted as ‘reply to a reply’.
- Which checkboxes display in the ‘Select only one action below’ column depends on factors such as the current status.

Steps

1. Click on **only one** of the ‘Select only one action below’ checkboxes or links per comment or reply.

   For details, see the Checkbox/Action section of Key Processes and Concepts.

2. Click **Save Changes**.

[43] A Comment Thread is one comment with one or more replies.

View My Comments screen elements

The following elements are featured on the View My Comments screen:

Field	How to Use	Description
Subject (Main Comment Thread)	Direct entry	Shown using filter, the subject (or title) of the comment.
Comment Thread Status	Drop-down list	Shown using filter, current assigned status for the comment
Document Section	Drop-down list	Shown using filter, section of document to locate.
My Threads	Click to select	Shown using filter, display only threads 'owned' by user.
All Participating Threads	Click to select	Shown by filter, display all threads.
Comments/Replies	n/a	Comment subject listing, by section.
Total Replies	n/a	Total number of replies for the associated comment.
Reqd/Reco (Required or Recommended)	n/a	Indicates if comment review is required or recommended, as selected on the Add Comment screen.
Changed Text	n/a	Checkmark indicates that there has been a change in section content (based on the published version of that section).

Reviewer (Organization)	n/a	Reviewer who made the comment and his/her organization.
Comment Status (Date)	n/a	Date current comment status was assigned.
Change Thread Status	Click checkbox or button	New status to be assigned to the thread.

View Screens - Appearance

Visual aids and change indicators featured on all of Review and Commenting's 'View' screens:

- Yellow lines separate the different threads.
- All comments are featured in gray, expanded text in white.
- A blue checkmark indicates that there has been a proposed change in section content (based on the published version of that section).
- A plus (+) sign to the left of a comment link indicates that the comment currently has at least one reply.

View Section Comments

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This is a major function for managing specific comments and their associated replies, based on the selected section. These sections are separated on the screen. Knowing this and other visual aspects of the screen appearance is important to understanding its functions.

Purpose

The View Section Comments screen is used to view comments and select further activities for that comments, such as adding a reply.

Key Processes and Concepts

- When applicable, a comment can be added to the selected section directly from this screen by clicking the **Add Comment** button.
- If a comment has a Show History link associated with it, clicking on the link displays the history of a previous discussion related to this comment.
- Which functions (additional resources) display when a comment link is clicked depend on the thread[44] status.

The following three Docu-MART Review & Commenting Status State Transition Diagrams illustrate the transitions that occur for each of the review tracks:

Status Transition Diagram - Pre-submission only

Status Transition Diagram - Sequential

Status Transition Diagram - Collaborative

Steps

If necessary, show all replies and comments for the selected comment by clicking on the plus (+) sign to the left of the link.

1. Click on the appropriate link.
2. Perform the required actions for the comment. The available button options that display for that comment depend on the thread status of the comment. For details, see Key Processes and Concepts.
3. Click **Save**.

Additional Screen Features

Attachments:

A comment marked with the **paper clip icon** indicates that the comment has an attachment.

1. Click the **link related to the icon**. The comment details are shown and the file name displays, as well as an associated View button.
2. Click on the **View** button to display the contents of the file attachment.

Optional: Click **File Attachment** to attach a file for the comment. The browser for this function works in the standard file location

[44] A thread is a comment and all of its replies. The Thread Owner is the person who made that comment.

manner. If there is an existing attachment, click the **Edit** link to access the comment and remove and/or change the attachment.

View Section Comments screen elements

The following elements are featured on the View Section Comments screen:

Field	How to Use	Description
Comments/Replies	Click link	Comment type and subject.
Total Replies	n/a	Total number of replies for the associated comment.
Reqd/Reco (Required or Recommended)	n/a	Indicates if comment review is required or recommended, as selected on the Add Comment screen.
Changed Text	n/a	Checkmark indicates that there has been a change in section content (based on the published version of that section).
Reviewer (Organization)	n/a	Reviewer who made the comment and his/her organization.
Comment Status (Date)	n/a	Date current comment status was assigned.
Change Thread Status	Click checkbox or button	New status to be assigned to the comment.

Printable Version

Clicking on the **Printable Version** button generates a printer-ready .pdf version of the document, or in another format if that was the method used for uploading the document.

Print using the Print selection from the Adobe Acrobat's File main menu, or click the small printer icon.

Document Review Timelines

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features

Introduction

This function is used in the manner of a progress report. It is an excellent reference function that illustrates the full scope and sequencing of the document's progress through the Review & Commenting process.

The screen is divided into two sections: **My Tasks**, which lists the major functional tasks for the logged-in user, along with the status for that task and its completion date, and **Document Review Timelines**, a table of stage tasks separated by Milestones and their related roles, Due Date, and Completed On Date.

Purpose

The Document Review Timelines screen is used to review the incomplete tasks for the user, as well as the due dates and milestones for the document.

Key Processes and Concepts

- The columns are sequenced by Due Date, with the soonest milestone on the left.
- Scroll to the right to see all columns. All columns might not be visible on the screen at one time.
- If a task has not been completed, the words ‘Not Complete’ appear instead of a date.
- The current task is delineated by a red arrow with the words ‘Current Task’ featured below it.
- The contents of this screen are dynamic. Since this is the only screen where all of the milestones appear at once, it should be viewed periodically.

Steps

1. This is a review-only screen, except for the secondary functions, as featured in the Additional Screen Features section:

Additional Screen Features

Tabs and Navigation buttons appear on this screen that allow easy navigation within Review and Commenting. **Note**: This screen does not contain all of the Navigation buttons listed.

Document and Reports buttons: Buttons that provide easy access to Document and Reports functions appear on the left side of the screen. Click on the appropriate button - the name of the button is also the name of the screen function that it displays.

Title Link:

1. Click the **Title** link to display identifying information for the document version, such as the full title, as well as Agents, Diseases, and file information. This file information includes the Document File and the PSW File, as well as any Additional Attachments.
2. Click the **View** button to the right of the file name to display view-only related information. For example, after clicking on the View button for 'PSW file', the PSW is displayed. Click the 'X' in the upper right corner to close this window.

Email Notification Selection Criteria

Clicking on one or both of the Review & Comment Activity Notification checkboxes and selecting an 'Option for email notification' from the drop-down list to indicate frequency provides a personalized notification system.

My Comment Thread (only) + a daily Email with a summary

Receive a daily summary email reporting activity on all comment threads started by this user and any replies made by any user on the thread.

Selected Sections (only) + a daily Email with a summary

Receive a daily summary email reporting activity on all of the selected sections, regardless of who created or who replied to the selected sections.

My Comment Threads And Selected Sections (both) + a daily Email with a summary

Receive a daily summary reporting activity on all comment threads started by this user and any activity on the selected sections, regardless of who created or who replied to the selected sections.

My Comment Threads (only) + Real Time (for each activity)

Receive an instant email notification each time there is any activity (reply, change in status, etc.) on a comment thread started by this user and any replies made by any user on the thread.

Selected Sections (only) + Real Time (for each activity)

Receive a instant email notification each time there is any activity on the selected sections only, regardless of who created or who replied to the selected sections.

My Comment Threads And Selected Sections (both) + Real Time (for each activity)

Receive an instant email notification each time there is any activity on thread created by this user and any activity on the selected sections, regardless of who created or who replied to the selected sections.

Reviewers Task Status

Purpose

This screen is a view only report listing the status of all reviewers for the submission.

Additional Features

Title Link:

1. Click the **Title** link to display identifying information for the document version, such as the full title, as well as Agents, Diseases, and file information. This file information includes the Document File and the PSW File, as well as any Additional Attachments.
2. Click the **View** button to the right of the file name to display view-only related information. For example, after clicking on the View button for 'PSW file', the contents of the PSW display. Click the 'X' in the upper right corner to close this window.

Set My Preferences

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

Email notification preferences are set on this screen. The 'My Comment Threads' checkbox and the 'Selected Sections' checkbox are used to select specific sections in the document that are to be included in the automatic email notification process.

If none of these checkboxes are checked, no commenting activity emails will be received. However, the appropriate selections can be checked or unchecked at any time.

Access to this screen is role[45]-based, with a task assigned for the protocol.

Purpose

The Set My Preferences screen is used to set preferred frequency and types of email notification.

Key Processes and Concepts

Preferences selected by the user will be set at each protocol document, version and submission level.

- The sections that appear for selection are the first-level headings from the document.
- My Comment Threads is user-specific.
- The My Comments Threads and Selected Sections functions can be chosen separately or they can work in conjunction. Understanding the contents and frequency of the emails to be sent is key to this notification process.
- Options for email notification is used to indicate if and when an email should to be sent when activity occurs on a thread.
  - **Daily Summary** indicates that at the beginning of each day an email with the entire thread of a user's comment on which some change was made on the previous day is sent to the thread owner.
  - **Real Time (for each activity)** occurs in real time. When a reply is added to a comment or reply, or when the Comment Thread status changes, an email is sent to the thread owner.

[45] For users with the role of Reviewer, Lead Reviewer, Site Coordinator, or Protocol Specialist.

- This screen will retain the selections after clicking **Save Preferences**, so current choices can be viewed at any time.

Steps

1. Click the checkbox for **My Comment Threads** to be notified when there is any activity on those threads.
2. To be notified when there is activity on selected sections:
   a. Click the **Selected Sections** checkbox.
   b. Scroll through and select the sections for email notification. Multiple section selections are allowed. The available sections are based on the current group template.
3. Using the 'Option for email notification' drop-down list, choose the appropriate email notification option.
4. Click **Save Preferences**.

Additional Features

The sections can be selected quickly using shortcut keys. For the PC, hold the **CTRL** key and select the sections. For the **MAC**, hold the COMMAND key and select the sections.

Title Link:

1. Click the **Title** link to display identifying information for the document version, such as the full title, as well as Agents, Diseases, and file information. This file information includes the Document File and the PSW File, as well as any Additional Attachments.
2. Click the **View** button to the right of the file name to display view-only related information. For example, after clicking on the View button for 'PSW file', the PSW document is displayed. Click the 'X' in the upper right corner to close this window.

Set My Preferences screen elements

The following elements are featured on the Set My Preferences screen:

Field	How to Use	Description
NCI Document #	n/a	Unique identifier for a document. If the document is submitted by a group, the group document number is used. If not, the identifier is system-

		generated.
Local Document #	n/a	Identifying code for this document, as determined by its initiating group
Version Date	n/a	Date to be associated with this version, defaults to current date.
Submission Type	n/a	Category or type of this submission, such as Pre-Submission[46] or CTEP Submission[47].
Roles	n/a	Function of the user for this protocol; such as Lead Reviewer, Reviewer, or Site Coordinator.
Title	Click link to display	Complete name of this document, as well as additional identifying information.
Notify me when there is activity on:	n/a	Prompts appropriate email notification.
My Comment Threads	Click checkbox	Indicates that the user wants to be notified when there is any kind of activity related to his/her own comments.
Selected Sections	Click checkbox	Indicates that the user wants to be notified any kind of activity on a selected section, regardless of the thread owner.
Option for email	Drop-down	Time and frequency of email

[46] When the document is finished it will be ready for internal reviewbefore it is submitted to CTEP.

[47] When the document is finished it will be CTEP-ready, and may or may not be submitted for internal review.

notification	list	notification regarding selections on the screen.

Accessing and Printing Docu-MART Reports

Introduction

Content-specific reports can be generated automatically by clicking on the appropriate button on the Review and Commenting main screen. All of the reports are per submission.

The following information contains the major function and contents of each, as well as any qualifying information, for the Reviewers Task Status, Comments Report, PRC Comments Report, Preview CTEP Consensus Review Report, Site Accepted Comments Report, Site Accepted Comments Report (Detailed), CTEP Consensus Review Report, CTEP Consensus Review Report (Detailed), Incorporated Comments Report, Previous Version Report, and Reconcile Report.

Steps to printing a report are featured at the end.

> **Note**: A comment marked with the **paper clip icon** indicates that the comment has an attachment. Click the related **link** to display the contents of the attached file in a new window.

Reviewers' Task Status shows the Reviewer's Group tasks separated by each reviewer's name and tasks.

- With the Sequential track, only the Reviewers belonging to their own group will be shown. That is, Site Reviewers, Lead Reviewer, and Site Coordinators see the Site Reviewers Status Report, while CTEP Reviewers, Lead Reviewer, and Protocol Specialist see the CTEP Reviewers Status Report.
- With the Collaborative track, both groups can see all reviewers participating in the submission.

Comments Report shows all comment threads, separated by section.

- With the CTEP Sequential track, discussions within another other Site group (ECOG, SWOG, and so on) cannot be seen by CTEP, while CTEP can see only the discussion within CTEP and the accepted comments by Site.
- Also with the CTEP Sequential track, the Site can see only the comments Submitted to them and their internal discussion.
- With the Collaborative track all comments can be seen by all except for the following three situations.
  a. Comments drafted by another reviewer are not shown.

b. Comments withdrawn will be shown only to the Reviewer who created it and to the Lead Reviewer
c. Comments Rejected are shown only to the Reviewer who created it and to Lead Reviewer.

PRC Comments Report shows comment information for the Protocol Review Committee.

- This report is populated from the Executive Summary, a Lead Reviewer function.
- It is sorted by section or reviewer, with the option of seeing only those comments associated with a specific reviewer. When sorting by reviewer, you can change the display order of your comments by clicking the **Assign Comments Rank** button.
- It the document is designated Collaborative and 'All' is selected from the Include Comments By Reviewer drop-down list, comments from CTEP and the Site will be included.
- The output can be in HTML or MS-Word. The choice is made by selecting the appropriate radio button.

Preview CTEP Consensus Review Report shows a draft version of the CTEP Consensus Review Report.

- It is available to the Lead Reviewer when the Submit Comments is the current task.
- After clicking Preview CTEP Consensus Review Report a Preview Consensus Report parameter screen is displayed.
- Select the Comment Status. The options include Added to CTEP CR and Marked for Rejection. Both of these reports display when All is selected from the drop-down list.
- Select the output format by clicking on the radio button associated with HTML or MS Word.
- Clicking Generate Report displays the report.

Site Accepted Comments Report shows all comments accepted by the participating group, separated by section.

- This report is only for the Site (such as ECOG and SWOG).
- It shows the comments that were ‘Accepted by’, as well as the participating group (such as ECOG or SWOG).

Note: These are the comments that may be incorporated into the document.

Site Accepted Comments Report (Detailed) shows all comments accepted by the participating group, with the name of the person who created the comment and the thread status, separated by section.

- This report is only for the Site (such as ECOG and SWOG).
- It shows the comments that were 'Accepted by', as well as the participating group (such as ECOG or SWOG).

  Note: These are the comments that may be incorporated into the document.

CTEP Consensus Review Report (Detailed) shows comments submitted to a participating group, with the name of the person who created the comment and the thread status, separated by section.

- This report is only for CTEP reviewers.
- It shows the comments that were 'Submitted to', as well as the participating group (such as ECOG or SWOG). The Name of the person who created comment and Thread Status also appears.

CTEP Consensus Review Report shows comments submitted to a participating group, separated by section.

- This report is available only for CTEP-Sequential track.
- It shows the comments that were 'Submitted to', as well as the participating group (such as ECOG or SWOG).
- When the CTEP Consensus Review Report button is clicked, a pop-up window is displayed for selecting HTML or MS-Word output.

Incorporated Comments Report shows the comments incorporated by the participating group.

- This report shows the comments that were 'Incorporated by', as well as the participating group (such as ECOG or SWOG).

Previous Version Report generates a specified report on a previous (or older) document version.

Reconcile Report allows the comments currently in the document to be compared to the comments that were recommended for inclusion. This provides a checklist function to help determine that all comments that should be included are included, and no more. The Reconcile Report is accessed by making selections on the Reconcile screen, a more detailed screen than the other reports.

> ***Note***: If a specific report button does not display, it is because the submission type does not support it.

Steps

1. Click the appropriate report button. The report generates automatically.

Printing a report:

Print using the Print selection from the File main menu, or click the small printer icon.

Reconcile Comments

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps

Introduction

This screen allows a section by section review of proposed new comments that are to be accept, added to, or rejected. It is a near-final step before resolving these outstanding comments.

The top part of the screen (above the blue vertical line) is the 'action and selection part', which is driven by the Filter function. Featured below the blue line is the 'display the results section'; the comments displayed are a result of the filtering selections.

Purpose

The Reconcile Screen is used to merge and/or finalize comments from the previous version with those of the current version.

Key Processes and Concepts

- It is mandatory that comments/changes initiated during the review of the previous document version are reconciled. Changes that other reviewers requested or that were unsolicited by CTEP, but incorporated by the Site, can also be reconcile.
- The available search criteria comes from previous sections.
- When opening the Reconcile screen for the first time, all comments are 'pending my review'.
- **Section Name** features CTEP-submitted comments from earlier versions. This function provides another way to access specific comments.
- **Section Name** will have 5 types of 'comment scenarios' to bring this section into the Section Name filter: CTEP Submitted Comments, Site Submitted Comments (with changes), Change sections, New sections, and Deleted sections.
- Comments within a comment thread are separated by a yellow line.

- Short cuts are provided for several comment-related screens, so that other functions related to reconciling can be accessed from this single screen.

Steps

1. Select an initial filtering option:

- Click **Show All** to view sections with comments that are pending reconciliation by all reviewers and comments that have already been reconciled.
- Click **Show Pending My Review** to view sections with comments that are pending reconciliation by you (the default).
- Click **Show Additional Filter(s)** to view more criteria that can be used to filter the list of comment:
    a. Select the appropriate reviewer from the **Comments reconciled by Reviewer** drop-down list.
    b. Click the appropriate checkboxes in **Include Sections**. Multiple options can be checked.
    c. In the **Section Name** section, select the appropriate section name from the drop-down list.
    d. In the **Change Type** section, un-click any of the default checkboxes that don't apply, and/or click any checkboxes that apply to select the change types to be included in the filter:

      X (Requested changes are not made in this section)

      ? (Please review. Changes incorporated, but may not be exactly as per comments)

      + (Unsolicited changes made by Site)

      = (Changes incorporated match proposed text)

   Note: Using the Change Type section efficiently provides an efficient way to view and process the comments. A colored icon (**X**, **?**, **+**, or **=**) appears to the left of each comment that displays after the filtering process is complete, to identify the change type.

2. Select the checkbox for the appropriate **Order By** option, Change Type or Document Sections.
3. Click **Search/Filter Results** to display all comments meeting the filter/search criteria. The results display below the blue line.

Results/Comments Section:

Note: You might want to click the **Reconcile Comments Completed** button after accessing this screen initially, in case there are any pending actions from the previous version.

1. Select the appropriate button to continue processing the select comment. After performing any additional actions, such as adding a comment, viewing the comment history, or viewing the document text, decide if the comment should be accepted or rejected.
2. Click the **Accept Changes Made** checkbox to accept the changes.
3. Click **Save** to save the changes to the Docu-MART database.

- ***or*** -

1. Click the Reject Changes Made and Propose Modifications[48] checkbox to reject the comment and display the Add Comment screen where the reason for rejection is to be added.

Continue rejecting or accepting comments. After all of the comments have been rejected or accepted:

1. Click **Save**.
2. Click **Reconcile Comments Completed**. If all of the comments have not been completed, that is, rejected or accepted, a warning message displays.

Note: After the Reconcile process is complete and closed, the information can be accessed using the Reconcile Report.

For further information:

Specific function-related information for the result/comment section, as well as supporting instructions, can be found in Processing the Reconcile Screen Comments Section.

The following topics contain information that should assist in understanding the scope and use of the Reconcile function:

Reconcile Scenarios

Reconcile Screen Details and Concepts

Reconcile Scenarios

The following information presents **potential** scenarios that might be relevant to using and understanding the Reconcile function.

Click the appropriate link to view a scenario based on the appropriate Change Type selection: Changes incorporated match proposed text,

[48] This option can be used to reject a rejection, in essence, negate the rejection and set the comment so that it can be accepted.

Requested changes are not made in this section, Please review Changes incorporated, but may not be exactly as per comments, or Unsolicited changes made by Site.

These are only a few likely scenarios, but they present a variety of relevant possibilities.

A. Scenario for **= Changes incorporated match proposed text**

   The setup: The section has only one CTEP submitted comment with proposed text changes from the previous CTEP submission and the comment's proposed text exactly matches the current version's section text.

   The process: Docu-MART displays the CTEP submitted comment and its proposed text changes fragments. It also displays the Site Accepted comment's description as the site response if it is different from the CTEP submitted comment's description. The text 'Changes made as per the proposed text' is displayed under the Changes Made in This Version label.

B. Scenario for **X Requested changes are not made in this section**

   The setup: The section has at least one CTEP submitted comment, with or without proposed text changes from the previous CTEP submission and no changes were made to the current version's section text when compared with the previous CTEP submission's text.

   The process: Docu-MART displays the CTEP submitted comment and its proposed text changes. It also displays the Site Accepted comment's description, if it is different from the CTEP submitted comment's description, or the rejected reason if the CTEP submitted comment was rejected as the site response. The text 'No changes made from the previous submission.' is displayed under the Changes Made in This Version label.

C. Scenarios for **? Please review. Changes incorporated, but may not be exactly as per comments**

   The setup: At the Document Level, one or more comments (with or without proposed text changes) were submitted by CTEP in the previous submission.

   The process: Docu-MART displays the CTEP submitted comment(s) and the proposed text changes. It also displays the Site Accepted comment's description if it is different from the

CTEP submitted comment’s description, or the rejected reason if the CTEP submitted comment was rejected as the site response. The text ‘These comment(s) are at the document level. Please review the entire document for the changes made’ is displayed under the Changes Made in This Version label.

The setup: The section has only one CTEP submitted comment, with or without proposed text changes from the previous CTEP submission, and some changes were made to the current version’s section text when compared with the previous submission’s text.

The process: Docu-MART displays the CTEP submitted comment and the proposed text changes. It also displays the Site Accepted comment’s description if it is different from the CTEP submitted comment’s description, or the rejected reason if the CTEP submitted comment was rejected as the site response. Under the Changes made in this version compared to proposed text label, Docu-MART displays the changed text of the current version that is different from the CTEP submitted comment’s proposed text. If the section is deleted from the current version, it displays the text ‘This section was deleted from the current version’.

The setup: The section has two or more CTEP submitted comments, with or without proposed text from the previous CTEP submission, and some changes were made to the current version’s section text when compared with the previous submission’s text.

The process: Docu-MART displays the CTEP submitted comments, along with the proposed text changes. It also displays the Site Accepted comment’s description, if it is different from the CTEP Submitted comment’s description, or the rejected reason if the CTEP Submitted comment was rejected as the Site response. Under the Changes made in this version compare to previous submission label, Docu-MART displays the changed text of the current version that is different from the previous submission. If the section is deleted from the current version it displays the text ‘This section was deleted from the current version’.

D. Scenarios for **+Unsolicited changes made by Site**

The setup: The section has no CTEP submitted comment(s) in the previous CTEP submission, and some changes were made to the current version’s section text when compared with the previous submission’s text.

The process: Docu-MART displays the Site Accepted comment's description(s), under the Site Comment(s) label. Under the Changes made in this version compared to previous submission label, Docu-MART displays the changed text of the current version that is different from the previous submission text.

The setup: The section has no CTEP submitted comment(s) in the previous CTEP submission, but the section was deleted from the current version.

The process: Docu-MART displays any Site Accepted comment's description(s), under the Site Comment(s) label. It displays the text 'This section was deleted from the current version' under the Changes made in this version compared to previous submission label. A button is provided to view the previous version. When the button is clicked, the system displays the previous version in a pop-up window bookmarked to the section that was deleted.

The setup: A new section is added in the current version.

The process: Docu-MART displays the text 'This new section was added by the Site' under the Changes made in this version compared to previous submission label. A button is provided to view the current version. When this button is clicked, the system displays the current version in a pop-up window bookmarked to the added section.

Reconcile Comments

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps

Introduction

This screen allows a section by section review of proposed new comments that are to be accept, added to, or rejected. It is a near-final step before resolving these outstanding comments.

The top part of the screen (above the blue vertical line) is the 'action and selection part', which is driven by the Filter function. Featured below the blue line is the 'display the results section'; the comments displayed are a result of the filtering selections.

Purpose

The Reconcile Screen is used to merge and/or finalize comments from the previous version with those of the current version.

Key Processes and Concepts

- It is mandatory that comments/changes initiated during the review of the previous document version are reconciled. Changes that other reviewers requested or that were unsolicited by CTEP, but incorporated by the Site, can also be reconcile.
- The available search criteria comes from previous sections.
- When opening the Reconcile screen for the first time, all comments are 'pending my review'.
- **Section Name** features CTEP-submitted comments from earlier versions. This function provides another way to access specific comments.
- **Section Name** will have 5 types of 'comment scenarios' to bring this section into the Section Name filter: CTEP Submitted Comments, Site Submitted Comments (with changes), Change sections, New sections, and Deleted sections.
- Comments within a comment thread are separated by a yellow line.
- Short cuts are provided for several comment-related screens, so that other functions related to reconciling can be accessed from this single screen.

Steps

1. Select an initial filtering option:

- Click **Show All** to view sections with comments that are pending reconciliation by all reviewers and comments that have already been reconciled.
- Click **Show Pending My Review** to view sections with comments that are pending reconciliation by you (the default).
- Click **Show Additional Filter(s)** to view more criteria that can be used to filter the list of comment:
    a. Select the appropriate reviewer from the **Comments reconciled by Reviewer** drop-down list.
    b. Click the appropriate checkboxes in **Include Sections**. Multiple options can be checked.
    c. In the **Section Name** section, select the appropriate section name from the drop-down list.
    d. In the **Change Type** section, un-click any of the default checkboxes that don't apply, and/or click any checkboxes

that apply to select the change types to be included in the filter:

X (Requested changes are not made in this section)

? (Please review. Changes incorporated, but may not be exactly as per comments)

+ (Unsolicited changes made by Site)

= (Changes incorporated match proposed text)

Note: Using the Change Type section efficiently provides an efficient way to view and process the comments. A colored icon (**X**, **?**, **+**, or **=**) appears to the left of each comment that displays after the filtering process is complete, to identify the change type.

2. Select the checkbox for the appropriate **Order By** option, Change Type or Document Sections.
3. Click **Search/Filter Results** to display all comments meeting the filter/search criteria. The results display below the blue line.

Results/Comments Section:

Note: You might want to click the **Reconcile Comments Completed** button after accessing this screen initially, in case there are any pending actions from the previous version.

1. Select the appropriate button to continue processing the select comment. After performing any additional actions, such as adding a comment, viewing the comment history, or viewing the document text, decide if the comment should be accepted or rejected.
2. Click the **Accept Changes Made** checkbox to accept the changes.
3. Click **Save** to save the changes to the Docu-MART database.

   - ***or*** -

1. Click the Reject Changes Made and Propose Modifications[49] checkbox to reject the comment and display the Add Comment screen where the reason for rejection is to be added.

Continue rejecting or accepting comments. After all of the comments have been rejected or accepted:

1. Click **Save**.

[49] This option can be used to reject a rejection, in essence, negate the rejection and set the comment so that it can be accepted.

2. Click **Reconcile Comments Completed**. If all of the comments have not been completed, that is, rejected or accepted, a warning message displays.

Note: After the Reconcile process is complete and closed, the information can be accessed using the Reconcile Report.

For further information:

Specific function-related information for the result/comment section, as well as supporting instructions, can be found in Processing the Reconcile Screen Comments Section.

The following topics contain information that should assist in understanding the scope and use of the Reconcile function:

Reconcile Scenarios

Reconcile Screen Details and Concepts

Processing the Reconcile Screen Comments Section

Note: Comments within a comment thread are separated by a yellow line.

Each section two checkboxes, Accept Changes and Reject/Propose Modifications.

First time the Reconcile Report is accessed, neither are checked) Comments are " reviewed by me and the changes are made by me" (for selection-type purposes).

- Each section also has **Add New Comment** and **View Document Section** buttons.
- Each comment within a section has a **View Comment History** button.

Descriptions and Directions for these five selections/options are:

- **Accept Changes** checkbox

  Indicates that the changes in the specific comment has been accepted.

- Reject/Propose Modifications checkbox

  Opens the **Add Comment** screen in another window. The reason for rejection is to be entered in the Add Comments section. After saving and returning to the Reconcile screen, the rejecting person's record is shown as a hyperlink.

- **Add New Comment** button

Opens the Add Comment screen in another window, where an additional comment can be added. This process is the same as when the comment was added originally.

- **View Document Section** button

  Displays the previous and current versions of the text in side by side screens.

- **View Comment History** button

  Displays the Comment Thread History screen, which includes the comment text for review purposes.

Reconcile - Expanded Comment Thread

Click link to advance to section or scroll down:

Introduction	Purpose	Steps

Introduction

This screen appears when the Reject Changes Made and Propose Modifications checkbox is clicked and a rejection comment already exists.

Purpose

The Reconcile - Expanded Comment Thread is used to reply within an Expanded Comment Thread before continuing the Reconcile process. This reply can contain information that qualifies a comment rejection.

Steps

1. Click **Reply to Comment** to enter a new reason or propose additional changes

   - ***or*** -

2. Click **OK with Comment** to agree with the pre-existing comments.

Reconcile Comments - Rejection

Click link to advance to section or scroll down:

Introduction	Purpose	Steps

Introduction

This screen provides the mechanism for entering the reason that the comment is being rejected. The rejection information will then be available on the Reconcile Screen.

Purpose

The Reconcile Comments - Rejection screen is used to enter an explanation of why the comment is being rejected as it currently is written. For the first person that rejects, the Add Comments screen displays. For others, the Final Reconcile – Expanded Comment Thread screen displays.

Steps

1. Type the reason for rejection in the **Add Your Comment** text box.
2. Click the appropriate button, **Save as Draft** or **Submit to CTEP**.

Note: The current proposed text changes also display.

Final Reconcile Comments

Click link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps

Introduction

This screen allows the Lead Reviewer in the Submit stage to finalize all proposed comments that are to be accept, added to, or rejected.

The top part of the screen (above the blue vertical line) features the filtering functions. Featured below the blue line is the 'display the results section'; the comments displayed are a result of the filtering selections.

Purpose

The Final Reconcile Comments screen is used to finalize comments in preparation for adding them to the CTEP Consensus Review.

Key Processes and Concepts

- The available search criteria comes from previous section.
- When opening the Reconcile screen for the first time, all comments are 'pending my review'.
- **Comments Selected by Reviewer is used to select the Reviewers whose comments are to display, while Include Sections is used to narrow the list of comments according a specific action by that reviewer.**
- **Pending File Reconcile is used to display what reconcile tasks are outstanding for you, the reviewer.**
- **Section Name** of the screen features CTEP-submitted comments from earlier versions. This function provides another way to access specific comments.
- **Section Name** will have 5 types of 'comment scenarios' to bring this section into the Section Name filter: CTEP Submitted Comments, Site Submitted Comments (with changes), Change sections, New sections, and Deleted sections.
- Comments within a comment thread are separated by a yellow line.
- Short cuts are provided for several comment-related screens, so that other functions related to reconciling can be accessed from this single screen.

Steps

1. Select an initial filtering option:

- Click **Show All** to view sections with comments that are pending reconciliation by all reviewers and comments that have already been reconciled.
- Click **Show Pending Final Reconciliation** to view sections with comments that are pending reconciliation by you (the default).
- Click **Show Additional Filter(s)** to view more criteria that can be used to filter the list of comment:
    a. Select the appropriate reviewer from the **Comments reconciled by Reviewer** drop-down list.
    b. Click the appropriate checkboxes in **Include Sections**. Multiple options can be checked.
    c. In the **Section Name** section, select the appropriate section name from the drop-down list.
    d. In the **Change Type** section, un-click any of the default checkboxes that don't apply, and/or click any checkboxes that apply to select the change types to be included in the filter:

X (Requested changes are not made in this section)

? (Please review. Changes incorporated, but may not be exactly as per comments)

+ (Unsolicited changes made by Site)

= (Changes incorporated match proposed text)

Note: Using the Change Type section efficiently provides an efficient way to view and process the comments. A colored icon (**X**, **?**, **+**, or **=**) appears to the left of each comment that displays after the filtering process is complete, to identify the change type.

2. Select the checkbox for the appropriate **Order By** option: Change Type or Document Sections.
3. Click **Search/Filter Results** to display all comments meeting the filter/search criteria. The results display below the blue line.

Results/Comments Section:

Note: You might want to click the **Reconcile Comments Completed** button after accessing this screen initially, in case there are any pending actions from the previous version.

1. Select the appropriate button to continue processing the select comment. After performing any additional actions, such as adding a comment, viewing the comment history, or viewing the document text, decide if the comment should be accepted or rejected.

Note: The **Accept All** button can be clicked to accept the changes to multiple sections at once, which have not been rejected by any reviewers. However, section comments that have been rejected and are pending final reconciliation must be reviewed and reconciled one at a time.

1. Click the **Accept Changes Made** checkbox to accept the changes. Note that the name of a reviewer who previously accepted the comment is also featured.
2. Click **Save** to save the changes to the Docu-MART database.

   - ***or*** -

1. Click the Reject Changes Made and Propose Modifications[50] checkbox to reject the comment. Note that the name of the rejecting reviewer is also featured, with a link that can be used to display the Final Reconcile Screen - Expanded Comment Thread screen that contains the rejected information.

[50] This option can be used to reject a rejection, in essence, negate the rejection and set the comment so that it can be accepted.

The screens that automatically display after rejection depended on several circumstances:

- If the changes were rejected by a reviewer, the **Final Reconcile Screen - Expanded Comment Thread** appears displaying the comment(s) entered by the other reviewers. .
- If you are the first reviewer to reject the changes, the **Modify for Consensus Review** screen appears.
- If the changes were rejected by a reviewer in the previous stage, the **Final Reconcile Screen - Expanded Comment Thread** window appears

Continue rejecting or accepting comments. After all of the comments have been rejected or accepted:

1. Click **Save.**
2. Click **Reconcile Comments Completed**. If all of the comments have not been completed, that is, rejected or accepted, a warning message displays.

Note: After the Reconcile process is complete and closed, the information can be accessed using the Reconcile Report.

For further information:

Specific function-related information for the result/comment section, as well as supporting instructions, can be found in Processing the Reconcile Screen Comments Section.

The following topics contain information that should assist in understanding the scope and use of the Reconcile function:

Reconcile Scenarios

Reconcile Screen Details and Concepts

Final Reconcile - Expanded Comment Thread

Click link to advance to section or scroll down:

Introduction	Purpose	Steps

Introduction

This screen displays after a rejection is applied to a comment thread. Further processing can then proceed from the options supplied by this screen.

Purpose

The Final Reconcile - Expanded Comment Thread is used to finalize a comment in preparation for adding it in the Consensus Review, unless the decision is made to reject it.

Steps

1. After reviewing the complete comment thread, select the appropriate option:

> **Note**: The available options depend on previous actions. If the Lead Reviewer had chosen to accept, **Reject Thread** is the only option. If the Lead Reviewer had chosen to reject the changes and the other reviewers have rejected the changes, the **Add to CTEP CR** and the **Modify & Add to CTEP CR** are the options.

- Select the comment that is a best fit to be added to the consensus review by clicking the **Add to CTEP CR** checkbox (featured in the 'Select only one action' column).
- If the comment it not acceptable as is, but it can be made suitable to be added to the consensus review, click the **Modify & Add to CTEP CR** button, which will then display the appropriate 'modify' screen.
- Click **Reject Thread** to reject the entire thread. After this button is clicked, a 'Reason' data entry box displays. Enter explanatory information for the comment thread rejection, then click **OK**.

Reconcile Screen Details and Concepts

Introduction

Docu-MART's Reconcile screen is used by CTEP reviewers to reconcile the comments against the revision/amendment version that is published for a CTEP sequential review. Both the current version and the previous version are Docu-MART authored documents. This screen's functions allow the CTEP reviewers to reconcile the comments that are submitted by CTEP in the previous CTEP submission review.

> **Note**: If the previous submission is closed early, before the Submit CR stage in a CTEP Sequential Review or before the Submit Comments by All stage in a collaborative review, the comments

that are submitted by CTEP in the CTEP Submission Review (prior to the early closed one) are reconciled.

Comment Types

Docu-MART's Reconcile function provides the ability to show the comments and changes to be reconciled, based on the following:

- Comments already reconciled by the Protocol Specialist.
- Comments already reconciled by a Reviewer.
- Comments where the proposed text matches with the changes in the current version.
- Comments where the proposed text does not match with the changes in the current version.
- Changes were made without a comment.
- Comments 'Accepted', 'Rejected' or 'Pending Review' by a Reviewer.

Processes

The Reconcile screen shows the changes made in the current version against the comments made in the previous version, or against the previous version itself.

Additionally, it allows the user to set his or her reconcile status to either Accepted or Rejected for each comment.

If a change is rejected, a new comment or reply can be added in the current version. The first reviewer who rejects the change adds a comment, and any subsequent reviewer who rejects the change adds replies. Later, if the reviewer changes the Reconcile Status on a comment to 'Accept', the comment will be removed, if there are no replies by other reviewers on this newly added comment. If the status is not changed to 'Accept', the user can add one more reply to indicate that the previously added comments or replies can be ignored.

The Reconcile screen will also:

- Show the other users' reconcile statuses.
- Allow the user to view the thread history of the comment.
- Track the overall Reconcile task completion.
- Allow the Lead Reviewer to Reconcile Comments during the Submit Comments task.
- Allow the Lead Reviewer to accept or reject comments that were already 'Accepted' or 'Rejected' by other reviewers.
- Enforce the Lead Reviewer to view the comments/replies added by other reviewers while reconciling, and provide an option to set

the status of the reviewer's reconcile thread to 'Add to CR', 'Modify and Add to CR', or 'Mark for Rejection'.

Docu-MART's Reconcile function **will not**:

- Allow the user to complete the Review and Commenting task if the Reconcile Comments task is not completed.

Reconcile Scenarios

The following information presents **potential** scenarios that might be relevant to using and understanding the Reconcile function.

Click the appropriate link to view a scenario based on the appropriate Change Type selection: Changes incorporated match proposed text, Requested changes are not made in this section, Please review Changes incorporated, but may not be exactly as per comments, or Unsolicited changes made by Site.

These are only a few likely scenarios, but they present a variety of relevant possibilities.

A. Scenario for **= Changes incorporated match proposed text**

   The setup: The section has only one CTEP submitted comment with proposed text changes from the previous CTEP submission and the comment's proposed text exactly matches the current version's section text.

   The process: Docu-MART displays the CTEP submitted comment and its proposed text changes fragments. It also displays the Site Accepted comment's description as the site response if it is different from the CTEP submitted comment's description. The text 'Changes made as per the proposed text' is displayed under the Changes Made in This Version label.

B. Scenario for **X Requested changes are not made in this section**

   The setup: The section has at least one CTEP submitted comment, with or without proposed text changes from the previous CTEP submission and no changes were made to the current version's section text when compared with the previous CTEP submission's text.

   The process: Docu-MART displays the CTEP submitted comment and its proposed text changes. It also displays the Site Accepted comment's description, if it is different from the CTEP submitted comment's description, or the rejected reason if the CTEP submitted comment was rejected as the site response. The text 'No changes made from the previous submission.' is displayed under the Changes Made in This Version label.

C. Scenarios for **? Please review. Changes incorporated, but may not be exactly as per comments**

The setup: At the Document Level, one or more comments (with or without proposed text changes) were submitted by CTEP in the previous submission.

The process: Docu-MART displays the CTEP submitted comment(s) and the proposed text changes. It also displays the Site Accepted comment's description if it is different from the CTEP submitted comment's description, or the rejected reason if the CTEP submitted comment was rejected as the site response. The text 'These comment(s) are at the document level. Please review the entire document for the changes made' is displayed under the Changes Made in This Version label.

The setup: The section has only one CTEP submitted comment, with or without proposed text changes from the previous CTEP submission, and some changes were made to the current version's section text when compared with the previous submission's text.

The process: Docu-MART displays the CTEP submitted comment and the proposed text changes. It also displays the Site Accepted comment's description if it is different from the CTEP submitted comment's description, or the rejected reason if the CTEP submitted comment was rejected as the site response. Under the Changes made in this version compared to proposed text label, Docu-MART displays the changed text of the current version that is different from the CTEP submitted comment's proposed text. If the section is deleted from the current version, it displays the text 'This section was deleted from the current version'.

The setup: The section has two or more CTEP submitted comments, with or without proposed text from the previous CTEP submission, and some changes were made to the current version's section text when compared with the previous submission's text.

The process: Docu-MART displays the CTEP submitted comments, along with the proposed text changes. It also displays the Site Accepted comment's description, if it is different from the CTEP Submitted comment's description, or the rejected reason if the CTEP Submitted comment was rejected as the Site response. Under the Changes made in this version compare to previous submission label, Docu-MART displays the changed text of the current version that is different from the previous submission. If the section is deleted from the current version it displays the text 'This section was deleted from the current version'.

D. Scenarios for **+Unsolicited changes made by Site**

The setup: The section has no CTEP submitted comment(s) in the previous CTEP submission, and some changes were made to the current version's section text when compared with the previous submission's text.

The process: Docu-MART displays the Site Accepted comment's description(s), under the Site Comment(s) label. Under the Changes made in this version compared to previous submission label, Docu-MART displays the changed text of the current version that is different from the previous submission text.

The setup: The section has no CTEP submitted comment(s) in the previous CTEP submission, but the section was deleted from the current version.

The process: Docu-MART displays any Site Accepted comment's description(s), under the Site Comment(s) label. It displays the text 'This section was deleted from the current version' under the Changes made in this version compared to previous submission label. A button is provided to view the previous version. When the button is clicked, the system displays the previous version in a pop-up window bookmarked to the section that was deleted.

The setup: A new section is added in the current version.

The process: Docu-MART displays the text 'This new section was added by the Site' under the Changes made in this version compared to previous submission label. A button is provided to view the current version. When this button is clicked, the system displays the current version in a pop-up window bookmarked to the added section.

All Review Options

Four groupings of Review and Commenting functions display after the **All Review Options** bar is clicked.

Document

Two options are available for overall document management:

Document Review Timelines	Displays the Document Review Timelines screen, containing the incomplete tasks for the user, as well as the due dates and milestones for the document.
View/Print Document	Displays the printer-read current document in .pdf form.

Comments

Comment actions can be initiated here, as well as displaying existing comments group in two different ways.

View/Add Comments	Displays the View Document – Add/Reply Comment screen; used for viewing the current document, as well as for adding and replying to specific document sections.
View My Comments	Displays the View My Comments report, which features comments and replies for a specific user's comment threads.
View All Comments	Displays the View All Comments report, which features all comments and replies for a document.

Others

Reviewers' Status Report	Displays the Reviewers Status Report, containing the task statuses based on Reviewer group.

Reports

All reports are per the document version. **Only those reports appropriate to the current role are featured on the screen.** They include:

My Comments Report	Shows the entire thread for any thread that a single Reviewer participated in or created.

Comments Report	Shows all comment threads, separated by section.
PRC Comments Report	For the Protocol Review Committee, this report is designed to provide comment information sorted by section or reviewer, with the option of seeing only those comments associated with a specific reviewer. Output can be in HTML or MS-Word.
Preview CTEP Consensus Review	Available to the Lead Reviewer when the Submit Comments is the current task, this report displays a draft version of the CTEP Consensus Review Report.
CTEP Consensus Review Report	Shows comments submitted to a participating group, separated by section. When the appropriate button is clicked, a pop-up window is displayed for selecting HTML or MS-Word output.
CTEP Consensus Review Report (Detailed)	Shows comments submitted to a participating group, with the name of the person who created the comment and the thread status, separated by section.
Site Consensus Review Report	Shows all comments accepted by the participating group, with the name of the person who created the comment and the thread status, separated by section.
Site Consensus Review Report (Detailed)	Shows all comments accepted by the participating group, separated by section.
Incorporate Comments Report	Shows the comments incorporated by the participating group.

Review and Commenting - Main Screen

Click the link to advance to section or scroll down:

Introduction	Purpose	Key Processes and Concepts	Steps	Additional Features	Screen elements

Introduction

This function provides an entry point for using the comprehensive functions featured in Review, Commenting and Reply.

The actions on this screen are task and role based, and some of the options on this screen are unique to each role. For example, all users have a View/Print Document option, while a Site Coordinator will have an Incorporate Comments option but a Lead Reviewer will not. However, a Lead Reviewer has a Resolve Comments option, which is not available to a Site Coordinator. There are other options that are role-specific. However, since the correct options are displayed automatically, no user intervention is needed.

Purpose

The Review and Commenting – Main screen is used to access and manage all of the document's Review, Commenting and Reply functions.

Key Processes and Concepts

- Available functions throughout the Review and Commenting process are role-dependent.
- There are two separate selection sections on this screen, Suggested Steps and All Review Options. Most of the Suggested Steps also appear in the All Review Options section, along with other Review and Commenting options.
- The Suggested Steps, as well as the actual sequential processes required by Review and Commenting, depend on a set of process rules. These are suggested, not mandatory steps. However, this section provides a shortcut to the most frequently used functions based on task stage, user role, and the overall status of the document.
- Many report selections featured on this screen are role-dependent.
- Tasks can be 'marked as completed', using the appropriate button on this screen. A helpful Task Completion Alert function displays when a task cannot be completed because a prior required step must be completed first.
- The Joint Commission on Accreditation of Healthcare Organizations maintains a list of misleading or unacceptable

terms to be avoided in medical documentation. This 'Do Not Use' list can be referenced by clicking on this link: Do Not Use List

Steps

1. Select the appropriate task from the Selected Task drop-down list (featured in the My Task Details section). There might only be only one available selection.
2. Choose one of the following initial actions, whichever is appropriate:
   - In the **Suggested Steps** section, click on the related button for the required activity. The appropriate screen displays based on the Suggested Steps selection.
   - In the **All Review Options** section, click on the related button for the required activity. The appropriate screen displays based on the All Review Options selection.

Additional Screen Features

Tabs and Navigation buttons appear on this screen that allow easy navigation within Review and Commenting.

On occasion it might be necessary to access application downloads.

Title Link:

1. Click the **Title** link to display identifying information for the document version, such as the full title, as well as Agents, Diseases, and file information. This file information includes the Document File and the PSW File, as well as any Additional Attachments.
2. Click the **View** button to the right of the file name to display view-only related information. For example, after clicking on the the View button for 'PSW file', the contents of the PSW display. Click the 'X' in the upper right corner to close this window.

Review and Commenting - Main Screen screen elements

Information about the buttons on this screen can be viewed at Suggested Steps and All Review Options.

The following elements are featured on the Review and Commenting Main screen:

Field	How to Use	Entry Method

NCI Document #	n/a	Unique identifier for a document. If the document is submitted by a group, the group document number is used. If not, the identifier is system-generated.
Local Document #	n/a	Identifying code for this document, as determined by its initiating group
Version (Date)	n/a	Date to be associated with this version, defaults to current date.
Submission Type	n/a	Category or type of this submission, such as Pre-Submission[51] or CTEP Submission[52].
Roles	n/a	Function of the user for this protocol; such as Lead Reviewer, Reviewer, or Site Coordinator.
Title	Click link to display	Complete name of this document.
	View only	Used as a 'You are here' marker.
Stage Tasks	n/a	Specific task and its current stage.
Due Date	n/a	Date assigned for task completion on the Create Timeline function.
Task Status	n/a	Current status of the task, such as 'Open' or 'Close'
Completed Date	n/a	Actual date of completion, might be different than due date.

[51] When the document is finished it will be ready for internal reviewbefore it is submitted to CTEP.

[52] When the document is finished it will be CTEP-ready, and may or may not be submitted for internal review.

Switch User To	Drop-down list	For Protocol Specialists and Site Coordinators, switches to functions for a delegated user.

Review & Commenting Main Screen Rules

Knowing the following rules, which are stage and task based, is key to using the Review and Commenting Main screen and understanding its processes:

For **individual Reviewers tasks** (Mass tasks, such as the Complete Initial Review & Comment task):

1. When the last user completing clicks the **Complete Initial Review & Comment** button before the task due date, the stage should be closed along with the last user's 'Review Comment & Reply' task (from the Selected Task option). When the last user completes his/her task for CTEP submission, the Site Coordinator gets an email notification to proceed to the next task- Submit Comments.
2. If the stage is Open and the due date has passed, that stage will be completed automatically.
3. When the last user is completing the task, an alert message appears. This message contains key information. For example, it might state that there are no comments or it might request confirmation to mark the task as complete.

For **multiple Reviewers tasks** (Group tasks, such as Resolve Comments, Submit Comments, and Incorporate Comments).

1. Until the task is completed the stage will be Open. The Reviewer must complete the task to complete the stage.
2. If one Reviewer completes the task then the stage is closed.
3. On completion of the Group Task, an email notification will be sent to the reviewers.

For **Submit Comments task** (CTEP Lead Reviewer)

1. If there are no comments submitted from both the Groups (Site and CTEP), then the 'Sign Off' is complete and the Review will be closed.
2. If there are Site submitted Comments and no CTEP submitted Comments, the 'Sign Off' is done and the review process will continue.

3. If there are CTEP submitted Comments 'with Recommendations', then the Sign Off is done with Recommended Comments and the review process will continue.

Note: To complete Current Task, all the previous tasks should be completed.

Suggested Steps

All Suggested Steps on the Review and Commenting main screen are featured here. However, since the Review and Commenting processes are role-based, **only those steps appropriate to the current role are featured on the screen**. They include:

Suggested Step	Action
Set My Preferences	Displays the Review and Commenting – Set My Preferences screen, used for setting an individual’s own preferences for the type and frequency of activity notification by email.
View/Print Document	Displays the document in printer-ready format.
Reviewers' Status Report	Displays the Reviewers' Status Report, containing status and task information, by reviewer, for the document.
Comments Report	Displays the Full Comments Report, which shows all comment threads, separated by section.
View/Add Comments	Displays the View Document – Add/Reply Comment screen; used for viewing the current document, as well as for adding and replying to specific document sections.
Assign Comments Rank	Displays the Rank Comments screen, which reviewers can use to give a rank number for the comments they enter. This option is available for the 'Review, Comment & Reply by CTEP' and 'Reconcile, Review, Comment & Reply' tasks.

Add Executive Summary	Displays the Executive Summary screen, designed for the Lead Reviewer to enter comments-related information that populates the PRC[53] Comments Report.
Resolve Comments	Displays the Resolve Comments screen, which shows all comments that need to be resolved.
Resolve Comments (Site Coordinator)	Displays the Resolve Comments-Site Coordinator screen, which shows all comments that need to be resolved. This Resolve Comments screen is exclusively for Site Coordinators.
Completed Resolve	If all comments are resolved, the status is changed to 'Completed'.
Completed Initial Review & Comment	Marks the Initial Review & Comment task as complete.
Submit Comments	Displays the Build Consensus Review screen in preparation for submitting the comments.
Completed Submit	If all comments are complete, the status is changed to 'Completed'.
The following three confirm options were developed as a shortcut to accessing the related Confirm screen, as well as serving as a reminder that confirmation is the appropriate next step. These options are unavailable or an error message may display if the stages do not meet the appropriate criteria.	
Confirm Consensus Review Comments	For **CTEP Lead Reviewer**, this step appears when the Review, Comment, and Reply by CTEP task is 'Complete', and the Submit Comments task is the current task but it is not completed.
Confirm Resolve Comments	For **Site Lead Reviewer**, this step appears when Review, Comment, and Reply task is 'Complete' (by All or by Site), and the Resolve

[53] Protocol Review Committee

	Comments task is the current task but it is not completed.
Confirm Incorporate Comments	For **Site Coordinator**, this step appears when the Review, Comment, and Reply task is 'Complete' (by All or by Site), and the Incorporate Comments task is the current task but it is not completed.

Confirm Consensus Review

This is the last chance to make a decision about adding a comment to the Consensus Review.

The comment then can be confirmed or the comment can be edited before confirmation.

Note: If the comment needs to be edited, click the **Edit** button to transfer to the Modify for Build Consensus Review screen.

1. Select one of the following options:
- Click **Confirm** to change the status to Confirmed.
- Click **Confirm & Previous** to change the status to Confirmed and transfer to the Build Consensus Review screen.
- Click **Previous** to transfer to the Build Consensus Review screen.
- Click **Confirm & Next** to change the status to Confirmed and transfer to the Rank Consensus Review Comments screen.
- Click **Next** to transfer to the Rank Consensus Review Comments screen.

An error message displays if comments are pending.

Additional Screen Features

Attachments:

A comment marked with the **paper clip icon** indicates that the comment has an attachment.

1. Click the **link related to the icon**. The comment details are shown and the file name displays, as well as an associated View button.
2. Click on the **View** button to display the contents of the file attachment.

Confirm Status

The Confirm Status appears with each Comment section. By default, the Not Confirmed comments, those with a status of 'No', are displayed.

To change the Comment Status type:

1. Click **Show Filter** in the Filter Criteria section.
2. Select one of the additional options from the Confirm Status drop-down list:
   - Yes: Shows all confirmed comments only.
   - All: Shows both Confirmed and Not Confirmed comments.
3. Click **Go**.

Optional: Click **Hide Filte**r to conceal the filtering function.

Confirm Incorporate Comments

This is the last chance to make a decision about incorporating a comment. The comment can then simply be confirmed.

1. Select one of the following options:
   - Click **Confirm & Previous** to confirm the comments that were "Marked for Incorporation" and "Marked to Not Incorporate" and transfer to the Incorporate Comments screen.
   - Click **Previous** to transfer to the Incorporate Comments screen.
   - Click **Confirm & Incorporate** to confirm the comments that were "Marked for Incorporation" and "Marked to Not Incorporate" and complete the Incorporate task.

   An error message displays if comments are pending.

Note: A comment marked with the **paper clip icon** indicates that the comment has an attachment. Click the related **link** to display the contents of the attached file in a new window.

Additional Screen Features

Attachments:

A comment marked with the **paper clip icon** indicates that the comment has an attachment.

1. Click the **link related to the icon**. The comment details are shown and the file name displays, as well as an associated View button.
2. Click on the **View** button to display the contents of the file attachment.

Confirm Status

The Confirm Status appears with each Comment section. By default, the Not Confirmed comments, those with a status of 'No', are displayed.

To change the Comment Status type:

1. Click **Show Filter** in the Filter Criteria section.
2. Select one of the additional options from the Confirm Status drop-down list:
   - Yes: Shows all confirmed comments only.
   - All: Shows both Confirmed and Not Confirmed comments.
3. Click **Go**.

Optional: Click **Hide Filte**r to conceal the filtering function.

Confirm Resolve Comments

Click link to advance to section or scroll down:

Purpose	Additional Features

Purpose

This is the last chance to make a decision about resolving a comment and preparing it for the incorporation process. The comment can then be confirmed or the comment can be edited before confirmation.

1. Select one of the following options:
   - Click **Confirm** to change the status to Confirmed.
   - Click **Confirm & Previous** to confirm the comments that were "Marked for Acceptance" and "Marked for Rejection" and transfer to the Resolve Comments screen.
   - Click **Previous** to transfer to the Resolve Comments screen.
   - Click **Confirm & Resolve** to confirm the comments that were "Marked for Acceptance" and "Marked for Rejection" and complete the Resolve task.

   An error message displays if comments are pending.

Notes:

- A comment marked with the **paper clip icon** indicates that the comment has an attachment. Click the related **link** to display the contents of the attached file in a new window.
- If the comment needs to be edited, click the **Edit** button to transfer to the Modify for Resolve Comments screen.

Additional Screen Features

Attachments:

A comment marked with the **paper clip icon** indicates that the comment has an attachment.

1. Click the **link related to the icon**. The comment details are shown and the file name displays, as well as an associated View button.
2. Click on the **View** button to display the contents of the file attachment.

Confirm Status

The Confirm Status appears with each Comment section. By default, the Not Confirmed comments, those with a status of 'No', are displayed.

To change the Comment Status type:

1. Click **Show Filter** in the Filter Criteria section.
2. Select one of the additional options from the Confirm Status drop-down list:
   - Yes: Shows all confirmed comments only.
   - All: Shows both Confirmed and Not Confirmed comments.
3. Click **Go**.

Optional: Click **Hide Filte**r to conceal the filtering function.

View Library Template

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

Use the View Library Template screen to view Library Template information such as the template parameters and the template elements that are used to create the Library Record.

Steps

Choose from the following actions:

- Click **Print** to print the current Template Parameters and elements on the screen.

- Click **Close** to close the View Library Template screen.

Data Elements

The screen displays the following information for the template parameters. The information varies based on the Area selected:

Area	Scientific or subject area that the template and its records are relevant to, e.g., Agents, Diseases, Adverse Events, etc.
Area – Sub Area (Version)	Sub category of the Area to further describe the template
Version	Version of the template
Long Name	Descriptive name of the template to help differentiate it from other templates
Owning Organization	Organization that owns the library template
Distributed by	Organization that distributes the agent(s) defined by the library template
Commercial/ Investigational	Indicates whether the content provided by the library records created from the template is investigational or commercial
IND Holder	The organization that holds the IND for the agents defined in the library records
Status	Status of the template version, e.g., Draft, Submitted for technical approval, active, etc.
Library Record Access Rule	Rule to define who can access the library records created based on the template

The screen displays the following information for the template elements:

Name and NSC	Reserved for the Agent name and NSC number for any records created based on this template
Element Name	User-specified element name
Hint	User-specified hint (optional)
XML Tag	XML tag to identify the format
Mandatory	Indicates whether the element is mandatory or optional

Library Templates

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

Use the Library Templates screen to view the list of available library templates and to display the actions that can be performed on them. The list of available library templates varies depending on your user role and your organization's affiliations.

Note: For information on user roles, see Scientific Library User Roles.

Steps

1. From the Library Templates screen, you can click the **Start** button to navigate to the Create Template screen, which allows you to create your own template and submit it for technical approval.
2. Alternatively, within the list of library templates that are displayed, you can choose from the following actions (which are available based on your user role by clicking the corresponding link in the **Action** column):

- Click **View** to display a pop-up of the View Library Template screen.
- Click **Submit for Technical Approval** to navigate to the Submit for Technical Approval screen (for CTEP Library Coordinators and Site Library Coordinators only).

- Click **Technically Approve** to navigate to the Technically Approve Template screen (for Technical Administrators only).
- Click **Activate** to navigate to the Activate Template screen (for CTEP Library Coordinators only).
- Click **Create New Version** to navigate to the Create Template Version screen (for CTEP Library Coordinators and Site Library Coordinators only).

Data Elements

The Library Templates screen displays the following information for each library template. The information varies based on the Area selected:

Area	Scientific or subject area that the template and its records are relevant to, e.g., Agents, Diseases, Adverse Events, etc.
Area – Sub Area (Version)	Sub category of the Area to further describe the template
Long Name	Descriptive name of the template to help differentiate it from other templates
Template Parameters	The following information is displayed under the column: 1. IND Holder 2. Commercial / Investigational 3. Distributed By
Owning Organization	Organization that owns the library template
Status	Status of the template version, e.g., Draft, Submitted for technical approval, active, etc.
Action	Actions that can be performed on the template, e.g., View, Edit, etc.

Select Library Template

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

The Library Content Provider and Library Coordinator use this screen to select the template from which to create the library record. This is the first step in creating the library record.

Steps

Choose from the following actions:

- Click the **View** link in the Action column to display the template with its elements and attributes in a new window.
- Click the **Select** button in the Choose Template column to navigate to the next step, "Create Library Record," with the suggested list of elements from the chosen template.

Data Elements

The Select Library Template screen displays the following information for each template:

Area – Sub Area (Version) – Long Name	Displays the values of Area – Sub Area and the version of the template - Long name of the template
Template Parameters	The following information is displayed under the column: 1. IND Holder 2. Commercial / Investigational 3. Distributed By
Owning Organization	Organization that owns the library template
Status	Status of the template version is Active
View	Contains a clickable link to view the selected template
Choose Template	Contains a Select button to navigate to the next

	step with the suggested list of elements from the chosen template

Create Template

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

The Library Coordinator uses the Create Template screen to create a Library Template, which then can be used to create library records that help to define Agents/Diseases while authoring the document.

The Library Coordinator selects the parameters used to create the template. The system displays suggested elements based on the Owning Organization and the Sub Area. The Library Coordinator then can add, modify, or delete the template elements. Once the template is created, the Library Coordinator can submit it for Technical Approval.

For CTEP-owned templates, the user who created the library template is notified via email when the library template is technically approved, activated, or rejected.

Steps

Choose from the following actions:

- Click **Save** to save the library record.
- Click **Save & Next** to save the library record and go to the next screen.
- Click **Print** to print the screen.
- Click **Cancel** to return to Browse Templates screen.
- Click **Add Element** to add a template element when no suggested elements exist.
- Click **Add Above** to add a template element above the selected element.
- Click **Add Below** to add a template element below the selected element.
- Click **Add Child** to add a template element as child.
- Click **Move From** and **Move To** to move elements from and to the selected place.

Note: The elements can be moved only within the same level.

Data Elements

The screen displays the following information for each library template. The information varies based on the Area selected:

Area	Scientific or subject area that the template and its records are relevant to, e.g., Agents, Diseases, Adverse Events, etc.
Long Name	Descriptive name of the template to help differentiate it from other template versions
Area – Sub Area (Version)	Sub category of the Area to further describe the template
Version	Version of the template
Owning Organization	Organization that owns the library template
Distributed by	Organization that distributes the agent(s) defined by the template
Commercial/ Investigational	Commercial OR Investigational
IND Holder	The organization that holds the IND for the agents defined in the library records
Library Record Access Rule	Rule to access the library record. It is defined at the template level, and can be overwritten at the record level.
Rule Description	Description of the access rule selected. It is defined at the template level and can be overwritten at the record level.
Valid For	Duration for which the records based on this template are valid. Can be overwritten at the record level.

The screen displays the following information for the template elements:

Name and NSC	Reserved for the Agent name and NSC number for any records created based on this template
Element Name	User-specified element name
Hint	User-specified hint (optional)
XML Tag	Suggested XML tag for elements added from the suggested list of elements. Elements that do not belong to the list of suggested elements are marked "Unknown."
Mandatory	Indicates whether the element is mandatory or optional
Display Order	The order of the elements displayed. Read-only field.

Create Template Version

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

Use the Create Template Version screen to create a Library Template version, which then can be used to create library records that help to define Agents/Diseases while authoring the document.

Based on the Library Template chosen to create a version the parameters are populated from the library template. The Library Coordinator can modify the Library Record Access Rule, Valid For and can add, modify, or delete the template elements. Once the template is created, the Library Coordinator can submit it for Technical Approval.

For CTEP-owned templates, the user who created the library template is notified via email when the library template is technically approved, activated, or rejected.

Steps

Choose from the following actions:

- Click **Save** to save the library record.
- Click **Save & Next** to save the library record and go to the next screen.
- Click **Print** to print the screen.
- Click **Cancel** to return to Browse Templates screen.
- Click **Add Above** to add a template element above the selected element.
- Click **Add Below** to add a template element below the selected element.
- Click **Add Child** to add a template element as child.
- Click **Move From** and **Move To** to move elements from and to the selected place.

> Note: The elements can be moved only within the same level.

Data Elements

The screen displays the following information for each library template version. The information varies based on the Area selected:

Area	Scientific or subject area that the template version and its records are relevant to, e.g., Agents, Diseases, Adverse Events, etc.
Long Name	Descriptive name of the template to help differentiate it from other template versions
Area – Sub Area (Version)	Sub category of the Area to further describe the template
Version	Version of the template
Owning Organization	Organization that owns the library template version
Distributed by	Organization that distributes the agent(s) defined by the template version

Commercial/ Investigational	Commercial OR Investigational
IND Holder	The organization that holds the IND for the agents defined in the library records
Library Record Access Rule	Rule to access the library record. It is defined at the template level, and can be overwritten at the record level.
Rule Description	Description of the access rule selected. It is defined at the template level and can be overwritten at the record level.
Valid For	Duration for which the records based on this template are valid. Can be overwritten at the record level.

The screen displays the following information for the template elements:

Element Name	User-specified element name
Hint	User-specified hint (optional)
XML Tag	Suggested XML tag for elements added from the suggested list of elements. Elements that do not belong to the list of suggested elements are marked "Unknown."
Mandatory	Indicates whether the element is mandatory or optional
Display Order	The order of the elements displayed. Read-only field.

Submit for Technical Approval

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

Library Coordinators can use this screen to view their defined template and submit it to the Technical Team for approval. This completes the second step in the template creation process. They can also return to the Edit Template screen to edit the template. The system sends an email notification to the Technical Team when the Library Coordinator submits the template.

Steps

Choose from the following actions:

- Click **Submit for Technical Approval** to submit the template for technical approval and send an email message to the Technical Team.
- Click **Edit Library Template** to navigate to the Edit Library Template screen, where you can delete the populated template elements and add your own template elements.
- Click **Print** to print the current Template Parameters and elements on the screen.
- Click **Cancel** to navigate to the List of Templates screen without saving any changes.

Data Elements

The Submit for Technical Approval screen displays the following information for each library template. The information varies based on the Area selected:

Area	Scientific or subject area that the template and its records are relevant to, e.g., Agents, Diseases, Adverse Events, etc.
Area – Sub Area (Version)	Sub category of the Area to further describe the template
Version	Version of the template
Long Name	Descriptive name of the template to help differentiate it from other templates

Owning Organization	Organization that owns the library template
Distributed by	Organization that distributes the agent(s) defined by the template
IND Holder	The organization that holds the IND for the agents defined in the library records
Status	Status of the template version, e.g., Draft, Submitted for technical approval, active, etc.
Library Record Access Rule	Rule to define who can access the library records created based on the template
Valid For	The length of time that the template will be valid once it is active. The time frame also indicates when the template will need to be reviewed by the owning organization.
Element Order	Order of the template elements
Element Name	Name for the template element
Hint	User-specified hint (optional)
XML Tag	XML tag to identify the format
Mandatory	Indicates whether the element is mandatory or optional

Technically Approve Template

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

Use the Technically Approve Template screen to review the submitted Library Template and to technically approve it. The Technical Team modifies the XML tags and makes sure the submitted Library Template conforms to the Docu-MART Authoring tool. Once the template is technically approved, the system notifies the CTEP Library Coordinator via email. For CTEP-owned templates, the user who created the library template is notified via email when the library template is technically approved, activated, or rejected.

Steps

Choose from the following actions:

- Click **Save & Technically Approve** to approve the Template technically.
- Click **Print** to print the current Template Parameters and elements on the screen.
- Click **Cancel** to navigate to the List of Templates screen without saving the changes.

Data Elements

The screen displays the following information for the template parameters. The information varies based on the Area selected:

Area	Scientific or subject area that the template and its records are relevant to, e.g., Agents, Diseases, Adverse Events, etc.
Area – Sub Area (Version)	Sub category of the Area to further describe the template
Version	Version of the template
Long Name	Descriptive name of the template to help differentiate it from other templates
Owning Organization	Organization that owns the library template
Distributed by	Organization that distributes the agent(s) defined by the template
Commercial/ Investigational	Indicates whether the content provided by the library records created from the template is investigational or commercial

IND Holder	The organization that holds the IND for the agents defined in the library records
Status	Status of the template version, e.g., Draft, Submitted for technical approval, active, etc.
Library Record Access Rule	Rule to define who can access the library records created based on the template

The screen displays the following information for the template elements:

Name and NSC	Reserved for the Agent name and NSC number for any records created based on this template
Element Name	Name for the template element
Hint	User-specified hint (optional)
XML Tag	XML tag to identify the format
Mandatory	Indicates whether the element is mandatory or optional

Activate Library Template

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

The CTEP Library Coordinator uses the Activate Library Template screen to view the Library Template and to either activate or reject it, but not to update any information. Once the template is activated, the system sends an email notification. For CTEP-owned templates, the user who created the library template is notified via email when the library template is technically approved, activated, or rejected.

Steps

Choose from the following actions:

- Click **Activate** to activate the template.
- Click **Reject** to reject the template. The system requires you to enter a reason.
- Click **Print** to print the current Template Parameters and elements on the screen.
- Click **Cancel** to navigate to the List of Templates screen without saving the changes.

Data Elements

The screen displays the following information for the template parameters. The information varies based on the Area selected:

Area	Scientific or subject area that the template and its records are relevant to, e.g., Agents, Diseases, Adverse Events, etc.
Area – Sub Area (Version)	Sub category of the Area to further describe the template
Version	Version of the template
Long Name	Descriptive name of the template to help differentiate it from other templates
Owning Organization	Organization that owns the library template
Distributed by	NCI/PMB or the organization you select
Commercial/ Investigational	Indicates whether the content provided by the library records created from the template is investigational or commercial
IND Holder	The organization that holds the IND for the agents defined in the library records
Status	Status of the template version, e.g., Draft, Submitted for technical approval, active, etc.

Library Record Access Rule	Rule to define who can access the library records created based on the template

The screen displays the following information for the template elements:

Name and NSC	Reserved for the Agent name and NSC number for any records created based on this template
Element Name	Name for the template element
Hint	Hint for the element
XML Tag	XML tag to identify the format
Mandatory	Indicates whether the element is mandatory or optional

View Library Record

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

Use the View Library Records screen to view library record information such as the template parameters and the library record elements.

Steps

Choose from the following actions:

- Click **Print** to save the screen contents and open the details in a new window that can be printed.
- Click **Close** to return to the previous screen.

Data Elements

The screen displays the following information for the Template elements:

Template Version	Version of the template on which the library record is based
Owning Organization	Organization that owns/creates the record
Distributed By	Organization that distributes the agent(s) defined by the library record
Commercial/ Investigational	Indicates whether the content provided by the library records created from the template is investigational or commercial
IND Holder	The organization that holds the IND for the agents defined in the library records
Status	Status of the library record, e.g., Draft, Submitted for technical approval, active, etc.

An example of the type of information that the screen displays for the Library Record elements follows:

Chemical Name	Chemical name of the element
Other Names	Other names for the element
Classification	Classification of the element
Molecular Formula	Molecular formula of the element
M.W.	Molecular weight of the element
Preparation	Preparation instructions for the element
Source	The source of the library record

Library Records

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

Use the Library Records screen to view the list of available library records and to display the actions that can be performed on them. The list of available library records varies depending on your user role and your organization's affiliations.

Some of the library record access rules are as follows:

- Library records that are restricted can only be accessed by users who are affiliated with the owning organization.
- Library records that are open to all can be accessed by users affiliated with any organization.
- Library records that are CTEP-approved LOI/Concept/Protocol records can only be accessed by users who are affiliated with an organization that is a Lead Organization on a CTEP-approved LOI/Concept/Protocol that has the library record's agent as one of the study agents.

Note: For information on user roles, see Scientific Library User Roles.

Steps

Within the list of library templates that are displayed, you can choose from the following actions (which are available based on your user role by clicking the corresponding link in the Action column):

- Click **View** to display a pop-up of the View Library Record screen.
- Click **Edit & Approve** to navigate to the Approve Library Record screen (for Site Library Coordinators only).
- Click **Edit & Activate** to navigate to the Activate Library Record screen (for CTEP Library Coordinators only).
- Click **Edit** to navigate to the Create/Edit Library Record screen (for CTEP Library Coordinators, Site Library Coordinators, and Library Content providers).
- Click **Edit & Submit for Approval** to navigate to the Approve Library Record screen (for Library Content Providers).
- Click **Edit & Submit for Activation** to navigate to the Activate Library Record screen (for Site Library Coordinators only).

Data Elements

The Library Records screen displays the following information for each library record:

Based on Template	Template on which the library record is based
Record Identifier	Classifying information such as the NSC number and name of the Agent
Owning Organization	Organization that owns the library template
Status	Status of the template version, e.g., Draft, Submitted for technical approval, active, etc.
Action	Actions that can be performed on the template, such as View

Create/Edit Library Record

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

Use the Create/Edit Library Record screen to create or edit the library record for the selected template.

Steps

The navigator (located just below the screen tabs) on the screen displays the three steps needed to create a library record:

1. Select Template (This is present only for Create Library Record).
2. Create Library Record (present only for Create Library Record) / Edit Library Record (present for Edit Record).
3. Submit for Approval (for Library Content Providers) OR

   Approve and Submit for Activation (for Library Coordinators) OR

   Activate (for CTEP Library Coordinators).

To create or edit a library record, the following are mandatory fields:

- Identifier for the Record, which is Agent Name/NSC for agents. Click the **Add** button to pick an agent from a list of agents. Once you have specified an Agent Name/NSC to a library record, the **Change** button appears, allowing you to change the record identifier.

Note: You can delete optional elements when creating a library record. The system displays a message to confirm the deletion. To add a deleted element back, click the **Add Element to Record** button next to the element.

Choose from the following actions:

- Click **Save** to save the library record.
- Click **Save & Next** to save the library record and go to the next screen which could be “Submit for Approval” OR “Approve and Submit for Activation” OR “Activate” based on the role as given above.
- Click **Print** to print the screen.
- Click **Cancel** to return to Library Records screen.

Data Elements

The Create/Edit Library Record screen displays the following information for each library record:

Area	Scientific or subject area that the template and its records are relevant to, e.g., Agents, Diseases, Adverse Events, etc.
Area – Sub Area (Version)	Sub category of the Area to further describe the template.
Long Name	Descriptive name of the template to help differentiate it from other templates. If you are creating more than one library record for the same NSC based on the same template, enter a Long Name that uniquely identifies each record.
Template Parameters	The following information is displayed under the column: 1. IND Holder 2. Commercial / Investigational

	3. Distributed By
Owning Organization	Organization that owns the library template.
Library Record identifier	Identifier for this library record. For Agents it is the NSC or Agent Name.
Valid For	The length of time that the record will be valid once it is active. The time frame also indicates when the template will need to be reviewed by the owning organization. The value defined at the record level must be less than or equal to the value defined at the template level.
Element	The name of the record element. For an Agent, one of the element's name is Chemical Name. You should provide details for this element.
Source	The source from where the details of the element are given.

The Create/Edit Library Record screen displays the following information for each library record:

Name and NSC	Reserved for the Agent name and NSC number for any records created based on this template.
Source	The source of the library record.

Create/Edit Library Record Version

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

Use the Create/Edit Library Record Version screen to create or edit the version of the library record.

Steps

The navigator (located just below the screen tabs) on the screen displays the three steps needed to create a library record:

1. Select Template (This is present only for Create Library Record).
2. Create Library Record (present only for Create Library Record) / Edit Library Record (present for Edit Record).
3. Submit for Approval (for Library Content Providers) OR

   Approve and Submit for Activation (for Library Coordinators) OR

   Activate (for CTEP Library Coordinators).

To create or edit a library record, the following are mandatory fields:

- Identifier for the Record, which is Agent Name/NSC for agents. This is obtained from the previous Library Record and is a display-only field in Create Library Record Version.

Note: You can remove optional elements when creating a library record.

Choose from the following actions

- Click **Save** to save the library record.
- Click **Save & Next** to save the library record and go to the next screen which could be "Submit for Approval" OR "Approve and Submit for Activation" OR "Activate" based on the role as given above.
- Click **Print** to print the screen.
- Click **Cancel** to return to Library Records screen.

Data Elements

The Create/Edit Library Record Version screen displays the following information for each library record. The library record details (Identifiers and elements) are obtained from the library record for which you are creating a version.

Area	Scientific or subject area that the template and its records are relevant to, e.g., Agents, Diseases, Adverse Events, etc.
Area – Sub Area (Version)	Sub category of the Area to further describe the template
Long Name	Descriptive name of the template to help

	differentiate it from other templates
Template Parameters	The following information is displayed under the column: 1. IND Holder 2. Commercial / Investigational 3. Distributed By
Owning Organization	Organization that owns the library template
Library record details	
Library Record identifier	Identifier for this library record. For Agents it is the NSC or Agent Name.
Valid For	Duration for which this record is valid. The value defined at the record level must be less than or equal to the value defined at the template level.
Element	The name of the record element. For an Agent, one of the element's name is Chemical Name. You should provide details for this element.
Source	The source of the library record.

Submit for Approval

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

Library Content Providers can use the Submit for Approval screen to submit library records for approval. This is the third and last step needed for the Library Content Provider to create a library record.

The Selected Template area of the screen displays selected template details such as the template name, version, and attributes. The Library

Record area of the screen displays the element names for the template and its values.

Steps

Choose from the following actions:

- Click **Edit Library Record** to navigate to the Create/Edit Library Record screen to edit the library record for the selected template.
- Click **Submit For Approval** to change the status of the Library Record to "Submitted for Approval." After the "Submit for Approval" is performed, you are redirected to the Library Records screen.
- Click **Cancel** to return to the Library Records screen without saving the changes.

Data Elements

The screen displays the following information for the Selected Template elements:

Template Version	Version of the template on which the library record is based
Owning Organization	Organization that owns/creates the record
Template Parameters	(The parameters can be the following for Area as Agent.)
Distributed By	Organization that distributes the agent(s) defined by the library record
Commercial/ Investigational	Indicates whether the content provided by the library records created from the template is investigational or commercial
IND Holder	The organization that holds the IND for the agents defined in the library records

The screen displays the following information for the Provide Restriction Library Record elements:

Library Record Access Rule	Indicates whether or not the rule defined in the template should be applied to this record.
Protocol Amendment Required	Indicates whether the protocol amendment is required (for Create Version of Library Record only)
Valid for	The duration for which the library record is valid

The screen displays the Library Record elements. The elements displayed are based on the information provided when the Library Record was created.

Approve Library Record

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

Library Coordinators can use this screen to view and approve the library record that was submitted for approval.

Steps

Choose from the following actions:

- Click **Save** to save the library record.
- Click **Edit Library Record** to navigate to the Create/Edit Library Record screen to edit the library record for the selected template.
- Click **Approve & Submit for Activation** to save, approve, and submit the library record for activation. This is available only to Site Library Coordinators. On approve the system returns you to the Library Records screen. The system notifies the CTEP Library Coordinator for the records to be activated via batch email.
- Click **Approve & Activate** to save, approve and then activate the library record. This is available only to CTEP Library Coordinator. On “Approve & Activate” the system returns to Library Records screen.
- Click **Print** to print the screen.

- Click **Cancel** to return to the Library Records screen without saving the changes.

Note: Only the person who created the library record or the Library Coordinator approving the record can edit it. The Library Coordinator can edit the record only after it is submitted for approval. Once the record is submitted, the person who created the library record can no longer edit it.

Data Elements

The screen displays the following information for the Selected Template elements:

Template Version	Version of the template on which the library record is based
Owning Organization	Organization that owns/creates the record
Template Parameters	(The parameters can be the following for Area as Agent.)
Distributed By	Organization that distributes the agent(s) defined by the library record
Commercial/ Investigational	Indicates whether the content provided by the library records created from the template is investigational or commercial
IND Holder	The organization that holds the IND for the agents defined in the library records

The screen displays the following information for the Provide Restriction Library Record elements:

Library Record Access Rule	Indicates whether or not the rule defined in the template should be applied to this record. By default this list shows the inherited access rule from the template. Selecting "No restriction" allows users from any organization to view this record.
Protocol	Indicates whether the protocol amendment is

Amendment Required	required (for Create Version of Library Record only)
Valid for	The duration for which the library record is valid
Source	The source of the library record

The screen displays the Library Record elements. The elements displayed are based on the information provided when the Library Record was created.

Activate Library Record

Click the link to advance to section or scroll down:

Purpose	Steps	Data Elements

Purpose

CTEP Library Coordinators can use this screen to either activate or reject an approved library record but not to update any information.

Steps

Choose from the following actions:

- Click **Activate** to activate the library record and return to Library Records screen.
- Click **Reject** to reject the library record and return to Library Records screen.
- Click **Print** to print the screen.
- Click **Cancel** to return to the Library Records screen.

Data Elements

The screen displays the following information for the Selected Template elements:

Template Version	Version of the template on which the library record is based
Owning Organization	Organization that owns/creates the record

Template Parameters	(The parameters can be the following for Area as Agent.)
Distributed By	Organization that distributes the agent(s) defined by the library record
Commercial/ Investigational	Indicates whether the content provided by the library records created from the template is investigational or commercial
IND Holder	The organization that holds the IND for the agents defined in the library records

The screen displays the following information for the Provide Restriction Library Record elements:

Library Record Access Rule	Indicates whether or not the rule defined in the template should be applied to this record.
Protocol Amendment Required	Indicates whether the protocol amendment is required (for Create Version of Library Record only)
Valid for	The duration for which the library record is valid
Source	The source of the library record

The screen displays the Library Record elements. The elements displayed are based on the information provided when the Library Record was created.

Scientific Library User Roles

CTEP Library Coordinators can view all organizations' Technically Approved and Active Library Templates.

Technical Administrators can access all organizations' Submitted for Technical Approval status Library Templates.

Site Library Coordinators, **Library Content Providers**, and **Docu-MART Users** can access their affiliated organizations' Library Templates.

The following table depicts the Scientific Library template roles and their access:

Scientific Library Template Roles and Their Access

Library Role	**Library Template Status**	**Actions**
CTEP Library Coordinator	Draft	View
		Edit
		Submit for Technical Approval
	Submitted for Technical Approval	View
	Technically Approved	View
		Activate
	Active	View
		Create New Version
	Rejected	View
		Edit
Site Library Coordinator	Draft	View
		Edit
		Submit for Technical Approval
	Submitted for Technical Approval	View

	Technically Approved	View
	Active	View
		Create New Version
	Rejected	View
		Edit
Technical Administrator	Draft	No Access
	Submitted for Technical Approval	View
		Technically Approve
	Technically Approved	No Access
	Active	No Access
	Rejected	No Access
Library Content Provider	Draft	View
	Submitted for Technical Approval	View
	Technically Approved	View
	Active	View
	Rejected	View
Docu-MART User will be able to view affiliated Organizations' Library Templates	Draft	View
	Submitted for Technical Approval	View
	Technically Approved	View

	Active	View
	Rejected	View

Release Notes

View-only information about each Docu-MART release is available in note form. Click on the link to open the Release Notes.

Version 1.0 Release 11.2 Notes 06/13/2008

Version 1.0 Release 11.3 Notes 04/14/2008

Version 1.0 Release 11.1 Notes 03/10/2008

Note: Release 11.1 changes are scheduled to be implemented in late June 2008.

Version 1.0 Release 11 Notes 01/24/2008

Version 1.0 Release 10 Notes 10/15/2007

Version 1.0 Release 9.2 Notes 09/14/2007

Version 1.0 Release 9.1 Notes 08/23/2007

Version 1.0 Release 9 Notes 08/03/2007

Version 1.0 Release 8 Notes 03/27/2007

Version 1.0 Release 7 Notes 12/29/2006

Version 1.0 Release 6 Notes 09/26/2006

Version 1.0 Release 5 Notes 07/07/2006

Version 1.0 Release 4 Notes 03/17/2006

Version 1.0 Release 3 Notes 02/22/2006

Version 1.0 Release 2 Notes 01/18/2006

Version 1.0 Release 1 Notes11/18/2005